Multiple Agency Fiscal Note Summary

Bill Number: 5263 SB Title: Psilocybin

Estimated Cash Receipts

NONE

Estimated Operating Expenditures

Agency Name		20	023-25			2	025-27			2027-29			
	FTEs	GF-State	NGF-Outlook	Total	FTEs	GF-State	NGF-Outlook	Total	FTEs	GF-State	NGF-Outlook	Total	
Office of Attorney General	Fiscal no	ote not availab	le										
Washington State Health Care Authority	.0	0	0	0	.0	0	0	0	.0	0	0	0	
Liquor and Cannabis Board	.0	0	0	0	.0	0	0	0	.0	0	0	0	
Department of Health	24.8	6,436,000	6,436,000	6,436,000	50.3	10,681,000	10,681,000	15,212,000	46.7	6,461,000	6,461,000	17,322,000	
Department of Agriculture													
Total \$	24.8	6,436,000	6,436,000	6,436,000	50.3	10,681,000	10,681,000	15,212,000	46.7	6,461,000	6,461,000	17,322,000	

Estimated Capital Budget Expenditures

Agency Name	2023-25				2025-27			2027-29	
	FTEs	Bonds	Total	FTEs	Bonds	Total	FTEs	Bonds	Total
Office of Attorney General	Fiscal r	note not availabl	e						
Washington State Health Care Authority	.0	0	0	.0	0	0	.0	0	0
Liquor and Cannabis Board	.0	0	0	.0	0	0	.0	0	0
Department of Health	.0	0	0	.0	0	0	.0	0	0
Department of Agriculture	.0	0	0	.0	0	0	.0	0	0
Total \$	0.0	0	0	0.0	0	0	0.0	0	0

Estimated Capital Budget Breakout

Prepared by: Breann Boggs, OFM	Phone:	Date Published:
	(360) 485-5716	Preliminary 2/8/2023

Individual State Agency Fiscal Note

Bill Number: 5263 SB	Title: Psilocybin	Agency	: 107-Washington State Health Care Authority
Part I: Estimates		•	
X No Fiscal Impact			
Estimated Cash Receipts to:			
NONE			
Estimated Operating Expend NONE	litures from:		
Estimated Capital Budget Im	pact:		
NONE			
	iture estimates on this page represent the n priate), are explained in Part II.	nost likely fiscal impact. Factors impacting	z the precision of these estimates,
	follow corresponding instructions:		
If fiscal impact is greate form Parts I-V.	r than \$50,000 per fiscal year in the co	urrent biennium or in subsequent bienn	iia, complete entire fiscal note
	nan \$50,000 per fiscal year in the curr	ent biennium or in subsequent biennia,	complete this page only (Part I)
Capital budget impact,	complete Part IV.		
Requires new rule making	ng, complete Part V.		
Legislative Contact: Mat	tthew Shepard-Koningsor	Phone: 360-786-7627	Date: 01/11/2023
Agency Preparation: Har	nh OBrien	Phone: 360-725-1447	Date: 01/31/2023
Agency Approval: Cat	rina Lucero	Phone: 360-725-7192	Date: 01/31/2023
OFM Review: Rob	yn Williams	Phone: (360) 704-0525	Date: 01/31/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

See attached narrative.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

See attached narrative.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

See attached narrative.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

NONE

III. B - Expenditures by Object Or Purpose

NONE

III. C - Operating FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part I and Part IIIA.

NONE

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.

NONE

Part V: New Rule Making Required Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

HCA Fiscal Note

Bill Number: 5263 SB HCA Request #: 23-031-3

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Senate Bill 5263 creates a system, which following a two-year program development period, individuals 21 years of age and older may consume psilocybin products under licensed service centers, under the supervision of licensed psilocybin facilitators.

New Section 4 is added to state this chapter may not be construed:

- (1) To require a government medical assistance program or private health insurer to reimburse a person for costs associated with the use of psilocybin products;
- (2) To prohibit a recipient of a federal grant or an applicant for a federal grant from prohibiting the manufacture, delivery, possession, or use of psilocybin products to the extent necessary to satisfy federal requirements for the grant.

II. B - Cash Receipts Impact

None

II. C - Expenditures

No fiscal impact.

Section 4(1) (2) of this proposed legislation appears to contain the content which is pertinent to the Health Care Authority (HCA). The proposed bill does not seek for HCA to create a reimbursement option for psilocybin products and related services.

Part IV: Capital Budget Impact

None

Part V: New Rule Making Require

None

Individual State Agency Fiscal Note

Bill Number: 5263 SB	Title:	Psilocybin	Agency:	195-Liquor and Cannabis Board
Part I: Estimates				
X No Fiscal Impact				
Estimated Cash Receipts to	0:			
NONE				
Estimated Operating Expo	enditures from:			
Estimated Capital Budget	Impact:			
NONE				
		this page represent the most likely fisco	al impact. Factors impacting	the precision of these estimates,
and alternate ranges (if app Check applicable boxes a				
If fiscal impact is grea	_	per fiscal year in the current bienniu	um or in subsequent bienni	a, complete entire fiscal note
form Parts I-V.	- 41 \$50,000			
	_	r fiscal year in the current biennium	or in subsequent blennia, o	complete this page only (Part I
Capital budget impac	•			
Requires new rule ma	aking, complete P	art V.		
Legislative Contact: M	Matthew Shepard-	Koningsor	Phone: 360-786-7627	Date: 01/11/2023
Agency Preparation: C	Colin O Neill		Phone: (360) 664-4552	Date: 01/17/2023
	Aaron Hanson		Phone: 360-664-1701	Date: 01/17/2023
OFM Review: A	my Hatfield		Phone: (360) 280-7584	Date: 01/18/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

The requirements of the Liquor and Cannabis Board ("agency") in the bill, as outlined below, are not expected to have a fiscal impact on the agency. This is based on the assumption that if the Liquor and Cannabis Board and Department of Health enter into an agreement permitting the Department of Health to utilize the Liquor and Cannabis Board's cannabis central reporting system (CCRS) under section 42 of the bill, then any costs incurred by the Liquor and Cannabis Board would be reimbursed by the Department of Health.

Section 6(h): The Washington psilocybin advisory board, established within the Department of Health, must include a person designated by the Liquor and Cannabis Board who has experience working with the cannabis central reporting system (CCRS).

Section 42(3): The Department of Health may enter into an agreement with the Liquor and Cannabis Board under which the Liquor and Cannabis Board permits the Department of Health to use the system developed and maintained by the Liquor and Cannabis Board to track cannabis products to track the transfer of psilocybin products between premises for which the department has issued licenses under this chapter, if the department determines this method is suitable, cost-effective, and not unduly burdensome. The department may enter into an agreement to purchase or license a tracking system used in another state, or it may develop its own system or set of procedures.

Section 81: The Liquor and Cannabis Board shall assist and cooperate with the Department of Health and the Department of Agriculture to the extent necessary to carry out the duties of the departments under this chapter.

Section 84(1): The Department of Health, the Department of Agriculture, and the Liquor and Cannabis Board may not refuse to perform any duty under this chapter on the basis that manufacturing, distributing, dispensing, possessing, or using psilocybin products is prohibited by federal law.

Section 85: A person may not sue the Department of Health, the Department of Agriculture, the Liquor and Cannabis Board, a member of the Liquor and Cannabis Board, or any employee of these entities, for performing or omitting to perform any duty, function, or power of the entity set forth under this chapter or in any other law of this state requiring these entities to perform a duty, function, or power related to psilocybin products.

Section 95(1): As is necessary to protect the public health and safety, and in consultation with the Liquor and Cannabis Board and the Department of Agriculture, the Department of Health shall adopt rules.

Section 104(1): As is necessary to protect the public health and safety, and in consultation with the Department of Agriculture and the Liquor and Cannabis Board, the Department of Health shall adopt rules establishing standards for the labeling of psilocybin products.

Section 106(1): As is necessary to protect the public health and safety, and in consultation with the Department of Agriculture and the Liquor and Cannabis Board, the Department of Health must adopt rules establishing standards for the packaging of psilocybin products.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

Section 42(3): The Department of Health may enter into an agreement with the Liquor and Cannabis Board ("agency") under which the Liquor and Cannabis Board permits the Department of Health to use the cannabis central reporting system (CCRS) developed and maintained by the agency to track cannabis products to track the transfer of psilocybin products between premises for which the department has issued licenses under this chapter, if the department determines this method is suitable, cost-effective, and not unduly burdensome. The department may enter into an agreement to purchase or license a tracking system used in another state, or it may develop its own system or set of procedures.

At this time, the Department of Health has indicated that they do not intend to utilize the agency's CCRS system to track psilocybin products. Therefore, there is no fiscal impact of this legislation to the agency.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures NONE

III. B - Expenditures by Object Or Purpose

NONE

III. C - Operating FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part I and Part IIIA.

NONE

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

 $Acquisition\ and\ construction\ costs\ not\ reflected\ elsewhere\ on\ the\ fiscal\ note\ and\ description\ of\ potential\ financing\ methods.$

NONE

IV. D - Capital FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

Individual State Agency Fiscal Note

_								
Bill Number: 5263 SB	Title:	Psilocybin			Agency: 30	03-Depar	tment of Health	
Part I: Estimates								
No Fiscal Impact								
Estimated Cash Receipts to:								
NONE								
Estimated Operating Expenditures	from:							
		FY 2024	FY 2025	2023-25	202	25-27	2027-29	
FTE Staff Years		16.2	33.4	24	.8	50.3	3 46	3.7
Account								
General Fund-State 001-1		2,003,000	4,433,000	6,436,00	00 1	0,681,000	6,461,0	00
Psilocybin Control and Regulation		0	C)	0	4,531,000	10,861,0	00
Account-State NEW-1								
To	otal \$	2,003,000	4,433,000	6,436,00	00 1	5,212,000	17,322,0	00
The cash receipts and expenditure esti	mates on	this nage represent the	e most likely fiscal	impact Factors i	mnacting the	nrecision	of these estimates	
and alternate ranges (if appropriate),	are explo	uined in Part II.	most tinety fiscul	impaci. Taciors i	mpacing inc	precision	of these estimates	,
Check applicable boxes and follow	corresp	onding instructions:						
X If fiscal impact is greater than \$ form Parts I-V.	550,000	per fiscal year in the	current bienniur	n or in subseque	nt biennia, c	omplete	entire fiscal note	•
If fiscal impact is less than \$50	,000 per	r fiscal year in the cur	rrent biennium c	or in subsequent	oiennia, con	nplete thi	s page only (Par	t I)
Capital budget impact, complet	te Part I	V.						
X Requires new rule making, con	nplete P	art V.						
Legislative Contact: Matthew Sl	hepard-l	Koningsor		Phone: 360-786	-7627	Date: (01/11/2023	
Agency Preparation: Donna Con	npton			Phone: 360-236			02/07/2023	
Agency Approval: Kristin Bett	tridge			Phone: 3607911	657	Date:	02/07/2023	

Breann Boggs

OFM Review:

Date: 02/08/2023

Phone: (360) 485-5716

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

The bill establishes a system for adults to access facilitated psilocybin (hallucinogenic mushroom) services regulated by the department. Individuals aged 21 or older would have access to psilocybin within licensed service centers or other permitted locations, under the supervision of licensed facilitators, and using products created and tested by licensed manufacturers and testers.

The bill directs the Department of Health (department) to:

- Convene a Washington Psilocybin Advisory Board with 19-21 members appointed by the Governor or designated by statute, to provide advice and recommendations to the department related to this new statute;
- Publish available research and information relating to the safety and efficacy of psilocybin;
- Develop 8 new credentials, including the establishment of necessary fees:
- 1. Psilocybin Products Manufacturer License
- 2. Psilocybin Products Manufacturer Microtier Endorsement
- 3. Psilocybin Service Center Operator License
- 4. Psilocybin Facilitator License
- 5. Psilocybin Facilitator Trainee License
- 6. Psilocybin Service Worker Permit
- 7. Psilocybin Service Facilitator Training Program/Course Approval
- 8. Psilocybin Testing Laboratory License
- Develop rules related to requirements to obtain and renew the credentials listed above;
- Develop and maintain a system for tracking the transfer and transportation of psilocybin products which prevents diversion, tampering, or substitution of psilocybin products and allows for accurate accounting and testing of those products
- Establish a social opportunity program at the department to help make the psilocybin industry equitable, inclusive, and accessible; and
- Develop a hotline or website to answer questions about licensed premises or premises for which an application has been submitted.

The bill also requires the department to do rulemaking to provide oversight on a number of issues, including the concentration of psilocybin and number of servings, transfer of licensed property, prohibiting certain advertising , administration of a psilocybin session, group administration sessions, client intake and information confidentiality, labeling, packaging, dosage requirements, product testing, possession limits, product tracking, and other requirements outlined in the bill.

Section 1: This bill requires the department to adopt rules for the implementation of a comprehensive regulatory framework that allows individuals 21 years of age and older in Washington State to be provided psilocybin services within licensed service centers by licensed facilitators and establishes an advisory board within the department to provide advice and recommendations to the department.

Section 5: Defines the two-year program development period as beginning September 1, 2023 and ending September 1, 2025.

Sections 6 – 7: Establishes the Washington Psilocybin Advisory Board (board) within the department to provide advice and recommendations to the department related to administration of this act. The board will have 19-21 members appointed by the Governor or designated by statute. During the two-year program development period, the board shall meet at least once every two calendar months. After the development period, the board shall meet at least once every calendar quarter. The bill grants the board authority to adopt rules and establish committees and subcommittees necessary for the operation of the board. The board may receive reimbursement or an allowance for expenses consistent with RCW 43.03.220

Bill # 5263 SB

(Compensation of members of part-time boards and commissions—Class one groups). The board must provide advice and recommendations to the department with respect to the administration of this chapter and the education of the public about psilocybin.

Sections 8-9: Specifies the department's duties, functions, and powers to include: providing the public available information relating to the safety and efficacy of psilocybin in treating mental health conditions; regulation of psilocybin products and services; licensing of psilocybin product manufacturing and sale, psilocybin services, or other licenses related to the consumption of psilocybin products; regulation of the use of psilocybin products and services; rulemaking necessary to carry out the intent and provisions of the bill and regulating advertising of psilocybin products; purchasing, possessing, seizing, transferring to a licensee, and disposing of psilocybin products as necessary to ensure compliance with the chapter and rules adopted.

Sections 10 – 12: The department may not issue any licenses under this chapter during the two-year program development period, except as otherwise provided by law. By September 1, 2023, the Governor shall appoint individuals to the Board, and by October 31, 2023, the Board shall hold its first meeting at a time and place specified by the department. By December 31, 2023, and from time to time thereafter, the department must publish and distribute to the public available studies, research, and other information relating to the safety and efficacy of psilocybin in helping behavioral health conditions. By December 31, 2024, the department shall adopt rules and establish forms necessary to implement this bill.

Sections 13 – 18: By January 2, 2024, the department shall begin receiving applications for the licensing of persons to: (1) manufacture psilocybin products; (2) operate a psilocybin service center; (3) facilitate psilocybin services; and (4) test psilocybin products. The department may require the fingerprints of any individual listed on an application for licensure for the purpose of requesting a state or nationwide criminal records check.

Sections 22 – 24: Establishes requirements for psilocybin manufacturer licenses. The department shall adopt rules requiring annual license renewals, establishing fees which may not exceed the cost of administering this chapter, and requiring psilocybin products be tested. Licensing fees shall be deposited in the Psilocybin Control and Regulation Account and may not exceed the cost of administering the chapter. The department must adopt rules designating different types of manufacturing activities, and a psilocybin product manufacturer may only engage in the type of manufacturing activity for which they have received an endorsement from the department. The department must create a microtiter manufacturing endorsement with license fees which are lower than the regular manufacturer license fees to reduce barriers to access. Only one application and license fee are required regardless of how many endorsements an applicant or licensee requests. The department may adopt rules restricting the quantities of psilocybin products at each manufacturing premise.

Sections 25 – 26: Establishes requirements for psilocybin service center operator licenses. Operation of psilocybin service centers is subject to regulation by the department, and psilocybin service centers are not health care facilities subject to chapter 70.37 RCW (Health care facilities). The department must adopt rules requiring annual renewal of service center operator licenses, establishing fees which may not exceed the cost of administering this chapter, establishing circumstances in which psilocybin services can be administered in the home of a client or other location permitted by the department, requiring operators to meet standards and best practices established by rule, and requiring psilocybin products sold by service center operators be tested. Licensing fees shall be deposited in the Psilocybin Control and Regulation Account and may not exceed the cost of administering the chapter. The department may adopt rules requiring service center operators use equipment to verify a person's age before providing psilocybin services.

Sections 27 – 29: Establishes requirements for psilocybin facilitator and facilitator trainee licenses, including supervision requirements. Facilitation of psilocybin services is subject to regulation by the department. The department must adopt rules requiring annual renewal of facilitator and facilitator trainee licenses, establishing fees which may not exceed the cost of administering this chapter, and prescribe requiring facilitators to meet standards and best practices established by rule. Licensing fees shall be deposited in the Psilocybin Control and Regulation Account and may not exceed the cost of administering the chapter. The department must offer an examination for facilitator license applicants at least twice per year. The department has authority to adopt rules establishing requiring a facilitator use an age verification scanner or other

equipment to verify a person's age before receiving psilocybin services.

Sections 30 - 36: Requires the department adopt rules establishing the requirements, specifications, and guidelines for providing psilocybin services, including client confidentiality, group administration sessions, the required preparation session, the required client information form, the administration session, and optional integration session.

Sections 37 – 41: Establishes the powers and duties of the department with respect to licenses. The department shall determine the qualifications, training, education, and fitness of applicants for licenses to facilitate the psilocybin services, formulate a code of professional conduct for psilocybin service facilitators, serve as the disciplinary authority for this chapter under the uniform disciplinary act (18.130 RCW), select licensing examinations for licenses to facilitate psilocybin services, and appoint representatives to conduct or supervise examinations of applicants for licenses to facilitate psilocybin services, and conduct inspections of the premises and the books of licensees. The department shall adopt by rule minimum standards of education and training requirements for psilocybin service facilitators and approve courses for psilocybin service facilitators.

Section 42: The department must develop rules prescribing procedures for licensees that allow for the tracking of psilocybin products from the point of manufacture to the point of sale to a client. The department is not required to direct the use of any particular technology, platform or system in rules, but must consider factors including cost, ease of administration by licensees, ease of compliance monitoring, and the time available in the two-year program development period and risk of causing delay to implementation of the system. The department may enter into an agreement with the Liquor and Cannabis Board (LCB) to use the system developed by LCB to track cannabis products.

Sections 43 – 48 & 61: Provides that the department has any power and may perform any function necessary to prevent the diversion of psilocybin products from licensees to a source not operating legally. In addition to disciplinary action available to the department under chapter 18.130 RCW (REGULATION OF HEALTH PROFESSIONS – UNIFORM DISCIPLINARY ACT) or this chapter, the department may immediately restrict, suspend, or refuse to renew a license if there is probable cause to conclude a licensee has purchased or received psilocybin products from an unlicensed source or sold psilocybin products in a manner not permitted by the licensee's license. The department may require a licensee or applicant provide a sworn statement showing information for all individuals with a financial interest in the business, and the department may refuse to issue, or may suspend, revoke, or refuse to renew, a license based on the actions of a person with a financial interest in the business. The department has authority to proceed with an investigation of a licensee or permit holder or action or disciplinary proceeding against a licensee or permit holder even if the license has lapsed, been suspended, or been revoked. The department has the authority to revoke, suspend, or restrict a license or require a licensee or licensee representative to undergo training. Licensees under this chapter are subject to the uniform disciplinary act (UDA) under chapter 18.130 RCW except as explicitly provided in this chapter or by rules promulgated by the department.

Section 62 – 65: Requires a permit issued by the department for an individual who participates in: the provision of psilocybin services; the possession, manufacturing, securing, or selling of psilocybin products; the recording of possession, manufacturing, securing, or selling of psilocybin products; or verification of identification documents. The department is required to issue permits to qualified applicants to perform this work and adopt rules establishing qualifications, the term of the permit, procedures for applying for and renewing a permit, applications, issuance, and renewal fees, training requirements. The department must conduct a criminal background check under RCW 18.130.064 (Authority and duties—Secretary and disciplining authority—Background checks) on an individual applying for a permit, and the department may require fingerprints for the purpose of requesting a state or nationwide criminal records check. Establishes whistleblower protections for employees of a licensee and requires the department to adopt rules to implement procedures for filing, investigation, and resolution of whistleblower complaints.

Sections 66 and 72: Creates the Psilocybin Control and Regulation Account. All receipts and fees collected, and civil penalties not to exceed \$5,000, issued under this chapter must be deposited into the account, and expenditures may be used only for the purpose of administration and enforcement of this chapter. The account is subject to allotment procedures, but an appropriation is not required for expenditures.

Sections 81 - 82: The Liquor and Cannabis Board and the Department of Agriculture shall assist and cooperate with the department to the extent necessary for the department to carry out the duties under this chapter.

Section 88: Creates the Client Bill of Rights, including the right of a client to report violations to these rights to the department or other appropriate governing body.

Section 92: The department must maintain a telephone hotline, website, or other effective means of communication for certain people to inquire if an address is the location of a licensed premises under this chapter or if an application has been submitted for license of the premises.

Sections 95 – 103: Establishes the requirements for psilocybin testing laboratory licensees and the department's enforcement authority over licensed laboratories. The department shall adopt rules in consultation with the Liquor and Cannabis Board (LCB) and the Department of Agriculture (WSDA). These rules establish standards for psilocybin products, including testing for microbiological contaminants, pesticides, solvents, and psilocybin concentration. The department may conduct random testing of psilocybin products. The department must adopt rules establishing qualifications to be licensed, including accreditation by the department, application and renewal processes, procedures for tracking, documenting, and disposing of products tested, fees which may not exceed the cost of administering this chapter, and annual renewal of licenses. Licensing fees shall be deposited in the Psilocybin Control and Regulation Account and must be reasonably calculated to pay the expenses incurred by the department under this chapter. The department may require the fingerprints of any individual listed on an application for the purpose of requesting a state or nationwide criminal background check. The department may inspect the premises and impose a civil penalty up to \$500 for each violation of sections 95 through 103 or a rule adopted to implement sections 95 through 103.

Section 104 - 111: In consultation with the LCB and the Department of Agriculture (AGR), the department must adopt rules establishing standards for the labeling and packaging of psilocybin products and may require a licensee to submit a label or packaging intended for use on a psilocybin product for preapproval by the department before the licensee may sell or transfer a psilocybin product bearing the label. The department may impose a fee for submitting a label or packaging for preapproval. The department must adopt rules establishing maximum concentrations per serving and number of servings permitted in a psilocybin product package; the rules must allow the facilitator and client to work out dosage, and the rules must not impose a maximum dosage of psilocybin that is less than 50 milligrams. To ensure compliance with these sections and rules adopted, the department may inspect the premises of a licensed manufacturer or service center, take action against a license, and impose civil penalties up to \$500 each day for violations.

Section 114: The department must create and administer a social opportunity program to help individuals who qualify as social opportunity applicants, including persons from distressed areas, persons who have a traditional or indigenous history with natural medicines, and persons who are veterans, and meet the requirements to become licensed under this chapter. The department may provide reduced license fees for social opportunity applicants at discount rates, which shall not increase the fee level borne by other applicants calculated according to RCW 43.70.250. The department may establish or facilitate the provision of scholarship funding for facilitator training.

Section 117: Amends the definition of "Controlled Substance" within 69.50 RCW (Uniformed Controlled Substances Act) to exclude psilocybin and psilocybin manufactured in accordance with this chapter.

Sections 120 – 123: Amends 18.130 (REGULATION OF HEALTH PROFESSIONS — UNIFORM DISCIPLINARY ACT) to include psilocybin service facilitators, and to exclude psilocybin services and activities provided for this this chapter from inclusion in RCW 18.130.180 (Unprofessional conduct.).

Section 124: Amends RCW 43.70.250 (License fees for professions, occupations, and businesses.) to exclude fees needed to implement the social opportunity program from the requirement to set fees for each program at a sufficient level to defray the costs of administering that program.

Section 127: Sets an immediate effective date for section 6 of this act, establishing the Washington psilocybin advisory board.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

This bill provides the department authority to establish and charge fees to administer this chapter. However, it also requires the department to establish a social opportunity program whereby applicants from distressed areas would pay discounted fees. The bill prohibits the department from charging higher fees to applicants from non-distressed areas to offset the lower fees paid by social opportunity program participants. It also exempts fees collected under the social opportunity program from meeting the requirements in RCW 43.70.250 for the cost of the department's licensing programs to be borne by licensees. As a result, the department will require a general fund state (GF-S) appropriation to recover the expenses of operating the psilocybin regulatory program. The size of the appropriation will depend on the rules adopted for the social opportunity program and the number of licensees who qualify from distressed communities. Although indeterminate at this stage, it could be significant.

Fees will be established through rulemaking which will begin in fiscal year (FY) 2024. All receipts, fees, and civil penalties collected will be deposited to the Psilocybin Control and Regulation Account.

ASSUMPTIONS:

- Due to the significant body of rulemaking required to implement the bill, the complexity of the rules in novel areas, and the need for extensive community engagement on rule development, the department anticipates it will not be ready to receive applications for licensure by the January 2, 2024 date required in Section 13 of the bill. The department assumes applications will be received beginning January 2, 2026.
- Oregon Health Authority (OHA) began accepting applications for licenses for psilocybin manufacturers, laboratories, service centers and facilitators on January 2, 2023. The department will have more data on the interest in psilocybin services and licensure as OHA continues licensing psilocybin services in Oregon. Unless otherwise noted, the estimated number of applications received in the first year is based on OHA forecasts and initial application data, adjusted for the difference in population between Washington and Oregon.
- According to "Psychedelic Drugs Market Global Industry Analysis (2018-2020) Growth Trends and Market Forecast (2021-2026)," the psychedelic drugs market is expected to grow at rate of 14.5% CAGR (compound annual growth rate) during the forecast period. Unless otherwise noted, the department assumes the same growth in licensees beginning in year 3 of licensing.
- Based on facility types licensed by the department, the department assumes an average renewal rate of 100% for facility types, unless otherwise noted.
- Washington Administration Code (WAC) 246-12-020 (3) states the initial credential will expire on the practitioner's birthday, except for faculty or postgraduate education credentials authorized by law. Initial credentials issued within ninety days of the practitioner's birthday do not expire until the practitioner's next birthday. Based on this WAC, the department assumes a standard 25 percent of first year applications for non-facility licenses will need to renew their license in the first year as their birthday will fall outside of ninety days from issuance of initial credential. Based on the average renewal rate for health professions, the department assumes a renewal rate of 98.5% for non-facility licenses beginning in the second year.
- The department will establish fees during rulemaking. During the rulemaking process, a detailed fee study will be prepared with proposed fees and provided for input by interested parties. The department will monitor the program fund balance and adjust fees.
- Because developing fees will require extensive community engagement and will be contingent on the social opportunity program and many factors which are unknown at this point, the cash receipts impact for license applications and renewals is INDETERMINATE.

APPLICATIONS AND RENEWALS:

Sections 13, 22 – 23, 25, 27, 63, 96:

Psilocybin Testing Laboratory License

Based on the number of applications OHA forecasts and the number of Washington State labs that perform cannabis testing, the department estimates 12 applications received in the first year and 4 applications each year for the next 3 years.

- FY 2026: 12 applications
- FY 2027: 4 applications, 12 renewals
- FY 2028: 4 applications, 16 renewals
- FY 2029: 4 applications, 20 renewals

Psilocybin Manufacturer License

The department estimates 70 applications received in the first year, an additional 50% in the second year, and annual growth of 14.5% each year thereafter.

- FY 2026: 70 applications
- FY 2027: 35 applications, 70 renewals
- FY 2028: 15 applications, 105 renewals
- FY 2029: 17 applications, 120 renewals

Psilocybin Manufacturer Microtier Endorsement

The department must adopt rules that designate different types of manufacturing activities, including the creation of a microtiter manufacturing endorsement with license fees which are lower than the regular manufacturer license fees to reduce barriers to access. Microtiter manufacturing activities will be determined during rulemaking starting in FY 2024. For the purpose of this fiscal note, the department assumes 6% of manufacturers will receive the Microtier Endorsement. This is based on the 6% of cannabis stores which are part of LCB's social equity program for the cannabis market.

- FY 2026: 4 applications
- FY 2027: 2 applications, 4 renewals
- FY 2028: 1 application, 6 renewals
- FY 2029: 1 application, 7 renewals

Psilocybin Service Center Operator License

The department estimates 55 applications received in the first year, an additional 50% in the second year, and annual growth of 14.5% each year thereafter. Based on facility types licensed by the department, the department assumes an average renewal rate of 100%.

- FY 2026: 55 applications
- FY 2027: 28 applications, 55 renewals
- FY 2028: 12 applications, 83 renewals
- FY 2029: 14 applications, 94 renewals

Psilocybin Facilitator License

The department estimates 344 applications received in the first year, 1,031 applications in the second year, and annual growth of 14.5% each year thereafter.

- FY 2026: 344 applications, 86 renewals
- FY 2027: 1,031 applications, 339 renewals
- FY 2028: 199 applications, 1,350 renewals
- FY 2029: 225 applications, 1,525 renewals

Psilocybin Facilitator Trainee License

A facilitator trainee may work in paid employment in the psilocybin industry in the capacity of a facilitator under the

supervision of a qualified supervisor. Qualified supervisors shall include all persons who have been licensed as psilocybin service facilitators for at least two years and other individuals as determined by the department. Until enough qualified supervisors are available, the department shall waive the supervised training requirement for individuals who it determines have acquired sufficient experience in psilocybin service facilitation through other means, in order to allow those individuals to be licensed as psilocybin service facilitators and to provide a supervision resource for trainees. Based on these requirements set forth in the bill, the department assumes it will begin receiving trainee applications beginning in year 3. Based on the average number of Substance Use Disorder Professional (SUDP) Trainee applications received each year as a percentage of SUDP licensees, the department assumes annual facilitator trainee applications received will equal 23% of the facilitator license base in that same year.

- FY 2028: 356 applications, 89 renewals
- FY 2029: 402 applications, 351renewals

Psilocybin Worker Permit

The department estimates 216 applications received in the first year, an additional 50% in the second year, and annual growth of 14.5% each year thereafter. The department assumes worker permits will be renewed annually.

- FY 2026: 216 applications, 54 renewals
- FY 2027: 108 applications, 213 renewals
- FY 2028: 47 applications, 316 renewals
- FY 2029: 53 applications, 357 renewals

Psilocybin Training Programs:

The department estimates 20 applications received in the first year, an additional 17 in the second year, and annual growth of 14.5% each year thereafter. The department assumes no renewals for training programs.

- FY 2026: 20 applications
- FY 2027: 17 applications
- FY 2028: 2 applications
- FY 2029: 2 applications

LABEL AND PACKAGING PREAPPROVAL FEE:

Sections 105 & 107: The department may require a licensee to submit psilocybin product labels and packaging for preapproval and may impose a fee for submitting a label or packaging for preapproval. The bill requires this fee be reasonably calculated to not exceed the cost of administering this section. Fees will be established during rulemaking starting in FY 2024. Due to the lack of reliable data to support assumptions on the volume of licensees the department may expect under this chapter and the resulting volume of labels and packaging which may require preapproval, the cash receipts impact of these sections is INDETERMINATE.

CIVIL PENALTIES:

Sections 72, 102, &111: The department may impose a civil penalty between \$500 and \$5,000 for each violation of a provision of this chapter or rule adopted under this chapter. Since licensees can appeal fines assessed, it is assumed that any penalties will be appealed. Therefore, the amount of revenue collected from the fines is unknown, and this component of cash receipts is INDETERMINATE.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

ASSUMPTIONS:

- Section 12 of the bill requires the department adopt rules and establish forms necessary to implement this bill by December 31, 2024. Due to the complexity of the rulemaking required to implement this bill, the department anticipates rulemaking will take 18 months to complete following a six-month period to hire and train staff. The department estimates the earliest rules could be adopted is September 1, 2025.
- Section 13 of the bill requires the department to begin receiving applications for licensing under this chapter by January 2, 2024. However, as stated above, the earliest the department will be able to adopt rules is September 1, 2025. Once rules are adopted, the department will have to modify its licensing system to accommodate the new license types and prepare to receive applications. As a result, the department anticipates the earliest it could begin receiving applications is January 2, 2026.
- Section 42 of the bill requires the department to track the movement of psilocybin products from the point of manufacture to the point of administration to a client in order to prevent product diversion and tampering. The department anticipates an information technology system is essential to fulfill these obligations, assure public safety, and meet reasonable public expectation for timely provision of records and information. The bill allows use of the Liquor and Cannabis Board's cannabis product tracking system. However, through consultation with LCB, the department understands the cannabis tracking system is not suitable for the this purpose. Therefore, the department assumes it will need to develop business requirements for a psilocybin tracking system, conduct a competitive procurement process, and implement a system. Based on experience with other information technology system deployments, the department expects it will take 3 years to complete this work from the point the rules are adopted. The department estimates the earliest the product tracking system could be operational is September 1, 2028.
- Because program implementation costs will be incurred prior to the collection of licensing and other fees intended to support administration of this chapter, the department assumes full implementation costs will be funded through General Fund-State (GF-S) appropriation.
- The department also assumes ongoing GF-S appropriation will be required to recover program expenditures. This is because the bill requires the department to establish a social opportunity program whereby applicants from distressed areas would pay discounted fees and prohibits the department from charging higher fees to applicants from non-distressed areas to offset the lower fees paid by social opportunity program participants. It also exempts fees collected under the social opportunity program from meeting the requirements in RCW 43.70.250 for the cost of the department's licensing programs to be borne by licensees.
- According to the "Psychedelic Drugs Market Global Industry Analysis (2018-2020) Growth Trends and Market Forecast (2021-2026)" report, the psychedelic drugs market is expected to grow at rate of 14.5% CAGR (compound annual growth rate) during the forecast period. The department assumes ongoing annual growth in the number of licensees and permitted workers will follow this forecast.

BOARD:

Sections 1, 5 – 7: The bill establishes the Washington Psilocybin Advisory Board within the department, made up of 19–21 members. The department anticipates ten (10) work group participants will be community representatives with lived experience who would not otherwise be compensated for their participation. Per RCW 43.03.220 (Compensation of members of part-time boards and commissions—Class one groups), the department will make available stipends of \$200 per meeting to these representatives. The bill requires the board meet at least once every two months during the two-year development period and once every calendar quarter after the development period, with no expiration. The board must meet at a time and place determined by the chair or a majority of the voting members of the board. Therefore, the department assumes the work group will have 5 meetings in FY 2024, 6 meetings in FY 2025, 5 meetings in FY 2026, and 4 meetings in FY 2027 and each year thereafter. In accordance with RCW 43.03.220, the department assumes all meetings will be held virtually in order to not require travel—while still maximizing member and public participation. For all meetings, the department anticipates providing meeting announcements and materials in English, Spanish, Russian, and Vietnamese, ASL and Spanish interpretation services, and Communication Access Realtime (CART) will be available for virtual attendees.

The Assistant Attorney General will provide legal advice on board formation and governance, board rulemaking, and bill implementation, including attending board meetings. Attorney General Office charges are estimated at \$12,000 in FY 2024,

\$8,000 in FY 2025, and \$7,000 each year thereafter.

Costs include Board stipends, translation, interpretation, CART services, and Assistant Attorney General services:

FY 2024: 0.1 FTE and \$35,000 (GF-S) FY 2025: 0.1 FTE and \$34,000 (GF-S)

FY 2026: \$29,000 (GF-S)

FY 2027 and ongoing: \$25,000 (Psilocybin Control and Regulation Account)

RULEMAKING:

Sections 1, 6, 8, 12, 22 – 23, 25, 27, 29, 30, 38, 42, 63, 65, 95, 96, 99, 104, 106, 108, 114, 117: There will be one-time rulemaking costs in FY 2024, and FY 2025 to adopt a new chapter of rules for: operation of the board; regulation of psilocybin products and services; establishing licensure procedures, requirements, approved training, examinations, fines, and fees; standards, regulations, and requirements for product testing, labeling, packaging, tracking, and advertising; whistleblower complaint procedures; and creation and administration of a social opportunity program. Additionally, the Pharmacy Quality Assurance Commission (commission) will adopt rules to align language in WAC 246-945-040 (Uniform Controlled Substance Act) to reflect changes made to the definition of Controlled Substance as it relates to psilocybin. Rulemaking in all areas must all take place concurrently, will be very complex and controversial, and will require knowledge in areas the department has no expertise (e.g., setting appropriate psilocybin concentrations and testing standards). The department will consult with the board, LCB, AGR, and outside experts for this additional knowledge. The department must establish project positions and hire 4 new FTE to conduct the rulemaking activities, a process expected to take six months due to current labor market conditions.

This bill requires the department to adopt rules establishing health and safety standards for psilocybin service centers, and licensing requirements for psilocybin manufacturers, service center operators, and testing laboratories. In compliance with RCW 70A.02.005, the HEAL Act, this bill would require a completion of an Environmental Justice Assessment for significant legislative rules with impact to the built environment. Environmental Justice Assessments require identification of strategies to ensure equitable distribution of environmental benefits and reduction of environmental harms as a result of this action. This is informed by the results of a cumulative impacts analysis to identify potential impacts to overburdened communities and vulnerable populations, input from engagement with overburdened communities and vulnerable populations, and directives from consultation with impacted tribes.

The department anticipates utilizing a rules project team—to conduct rulemaking to implement this bill. This team will consist of 3 policy staff, a rules project manager, and a community engagement specialist to identify underreached communities and engage them in the rulemaking process. The community engagement process will focus on identifying specific groups who have previously experienced barriers to participating in the department's rulemaking efforts and conducting outreach to these groups. The department will hold additional workshops and listening sessions to engage disadvantaged communities which have historically not benefited from past policies which placed additional barriers to access. The department will seek to include veterans and persons with traditional or indigenous history with natural medicines in the rulemaking process, which will include collaboration with Washington State Tribes.

The rulemaking process will include 6 listening sessions, 12 meetings with interested parties, and 4 formal rules hearings. The listening sessions and rules hearings will be held in-person, in both Eastern and Western Washington, and will also have a virtual attendance option. All interested parties meetings will be held virtually. Rulemaking will take at least 18 months to complete. For all meetings, the department anticipates providing meeting announcements and materials in English, Spanish, Russian, and Vietnamese, ASL and Spanish interpretation services, and Communication Access Realtime (CART) will be available for virtual attendees.

Due to the controversial nature of the rulemaking, the department anticipates increased attendance of the rules hearings, and larger than normal facilities and security will be required. Due to this complexity and the controversial nature of creating a regulatory framework for the use of a Schedule I drug, the department will use a contracted facilitator at the workshops and rule hearings.

One-time facilitator, outside expertise, and security are \$70,000, \$80,000, and \$30,000 respectively for a total \$180,000 in personal service contracts. Additionally, one-time rulemaking costs include staff, travel, facilities, translation and interpretation services, and associated expenses (including goods and services, travel, IT equipment, intra-agency, and indirect charges), and Assistant Attorney General support in the amount of \$25,000:

FY 2024: 3.0 FTE and \$445,000 (GF-S) FY 2025: 5.6 FTE and \$861,000 (GF-S) FY 2026: 0.9 FTE and \$113,000 (GF-S)

TESTING STANDARDS:

Sections 11 and 95: The department will require the expertise of a Toxicologist 3 to support rulemaking on psilocybin testing standards. Based on the level of toxicology consultation provided for the development of LCB and department cannabis rules, as well as the experience in Oregon, the department assumes it will require 0.5 FTE Toxicologist 3 in FY 2024 and 0.2 FTE in FY 2025 to assist in establishing standards for testing psilocybin products and identifying appropriate tests for psilocybin products.

Total one-time costs for a Toxicologist 3 to support testing standards rulemaking:

FY 2024: 0.7 FTE and \$101,000 (GF-S) FY 2025: 0.3 FTE and \$40,000 (GF-S)

HEALTHCARE ENFORCEMENT MODERNIZATION SOLUTION (HELMS):

Sections 13, 18, 22 – 23, 25, 27, 38, 63, 96, 99: Implementation of this bill will require the department to modify the Healthcare Enforcement and Licensing Modernization System (HELMS). Work will include creating new applications, configuring the new credentials, updating reports, and updating databases for psilocybin manufacturer, psilocybin manufacturer microtier endorsement, psilocybin service center operators, psilocybin service facilitators, psilocybin facilitator trainees, psilocybin worker permits, department approved training programs, and psilocybin testing laboratories.

One-time department staff for implementation:

- IT Application Development 0.1 FTE
- IT System Administration 0.3 FTE
- IT Business/Quality Analyst 0.2 FTE
- IT Data Management 0.1 FTE

Ongoing staff for maintenance and operations:

- IT Application Development 0.04 FTE
- IT System Administration 0.09 FTE
- IT Business/Quality Analyst 0.04 FTE
- IT Data Management 0.02 FTE

One-time implementation costs will be 1.0 FTE and \$134,000 (GF-S) in FY 2026. Starting in FY 2027, ongoing maintenance and operations costs will be 0.3 FTE and \$40,000 (Psilocybin Control and Regulation Account).

LICENSING:

Sections 1, 8, 10, 13 – 18, 22 – 23, 25, 27 – 28, 37 – 38, 63, 96, 99: This bill requires additional staff to create application forms for the new credentials, review and process initial applications, run background checks on all new applicants, provide technical assistance to licensees, issue licenses and permits for qualified applicants, process renewals, conduct facilitator exams, facilitate the telephone hotline and answer inquiries, review and approve training programs, and pre-approve product labeling and packaging. There is also impact to the Office of Customer Service (OCS) operations, call center, and revenue units as a result of the increase in applications and renewals. The department will begin hiring new staff in FY 2025 to allow

time for training, preparation for licensing activities, and approval of initial training programs. Additional OCS staff will be hired six months before licensing begins to allow time for training.

Licensing staff will include:

- Licensing Manager 1.0 FTE
- Licensing Program Support 1.0 FTE
- Social Opportunity Program Support 1.0 FTE
- Permit Administrator 1.0 FTE
- Labeling and Packaging Technical Assistance 1.0 FTE

OCS Licensing support staff (average annual):

- Call Center/Front Counter/Renewals/Revenue Staff 0.2 FTE
- Credentialing Staff 1.3 FTE

Licensing fiscal impacts are based on the licensing assumptions detailed in the fiscal note section II. B - Cash Receipts Impact, however these estimates are based on extremely limited data. If psilocybin licensing levels exceed the department's estimates, additional program staff beyond what is identified will be required to support the psilocybin services licensing workload.

The department assumes it will contract out work related to the development of the psilocybin facilitator licensure examination as there is no nationally recognized body for this profession. Based on other contracts the department has with testing agencies for other professions, the department estimates one-time costs of \$30,000 for the creation of the exam and annual costs of \$6,000 for exam administration.

Costs include staff, associated costs (goods and services, IT equipment, intra-agency, and indirect charges), and exam vendor charges:

FY 2025: 6.9 FTE and \$827,000 (GF-S)

FY 2026: 9.1 FTE and \$1,078,000 (GF-S)

FY 2027: 9.3 FTE and \$1,067,000 (Psilocybin Control and Regulation Account)

FY 2028: 8.6 FTE and \$1,001,000 (Psilocybin Control and Regulation Account)

FY 2029 and ongoing: 8.7 FTE and \$1,006,000 (Psilocybin Control and Regulation Account)

COMPLIANCE:

Sections 9, 37, 39, 42 – 47, 56 – 61, 86, 95 – 96, 98 – 102, 109 – 111, 120 – 122: The bill requires staff to regulate psilocybin activities and ensure compliance with this act, the Uniform Disciplinary Act (chapter 18.130 RCW), and rules adopted by the department. This requires staff to perform inspections of premises upon initial application and annual renewal and to ensure compliance, conduct random testing of psilocybin products, respond to public records requests, receive and assess complaints of noncompliance, perform complaint investigations, open discipline cases, perform case disposition, and adjudicate discipline cases.

Based on the department's experience with the implementation of the medical cannabis program, the department assumes high discipline rates for the first 4 years of licensing. Based on the department's lack of experience licensing manufacturing facilities, the department assumes psilocybin manufacturers and service centers will have enforcement rates similar to pharmacies. Based on these assumptions and the estimated number of licensees, the department estimates it will receive 14 complaints per year for the first four years for manufacturers and service centers, resulting in an estimated 4 discipline cases in FY 2027 and 6 discipline cases each year thereafter.

Based on the bill's prohibition on requiring a degree from an institution of higher education for a psilocybin service facilitator and the limited scope of the training to be required of a psilocybin worker, the department assumes licensed facilitators,

facilitator trainees, and permitted workers will have discipline rates similar to other professions with no degree requirement and limited training programs, such as nursing assistants. Based on these assumptions, the department estimates it will receive 152 complaints per year against psilocybin facilitators and workers, resulting in an estimated 65 discipline cases in FY 2027 and 67 discipline cases each year thereafter.

Due to the small number of estimated licensees and the nature of the scope, the department assumes no discipline for testing labs.

The complaint response process includes five steps: 1) intake, 2) assessment, 3) investigation, 4) case disposition, and 5) adjudication. Staff review the complaint, identify the history of the facility complained about, and help assess whether an investigation is warranted. The investigator obtains information about the complaint and the respondent and then prepares a report detailing the findings. After investigation, the department decides whether to pursue legal action. Staff attorneys, paralegals, assistant attorney general and other staff work to develop the legal documents and charge the violation. Most cases are settled, and the staff attorney manages that process. If the respondent asks for a hearing, staff must schedule the hearing, and the health law judge considers all legal motions, presides over the hearing, and drafts the final order. The Office of the Attorney General represents the department at hearings and may provide advice throughout the enforcement process.

Compliance staff will include:

- Compliance Manager 1.0 FTE
- Manufacturing Facility Inspector/Investigator 2.0 FTE
- Testing Laboratory Inspector/Investigator 2.0 FTE
- Service Center Inspector/Investigator 2.0 FTE
- Toxicologist 1.0 FTE
- Health Profession Investigator 0.7 FTE
- Compliance Administrative Staff 0.5 FTE
- Paralegals, Clerks, and Legal Secretaries 0.4 FTE
- Public Disclosure Analysts 0.2 FTE
- Staff Attorneys and Health Law Judges 0.2 FTE

The department will begin hiring new staff 6 months before it begins accepting applications to allow time for training and preparation for premises inspections.

The estimated cost of compliance is highly dependent on the licensing assumptions detailed in the fiscal note section II. B - Cash Receipts Impact. However, these estimates are based on extremely limited data. If psilocybin licensing and discipline rates exceed the department's estimates, additional program staff beyond what is identified will be required to support the psilocybin services discipline workload.

Costs include staff, associated costs (goods and services, IT equipment, intra-agency, and indirect charges), and Assistant Attorney General service in the amount of \$16,000 in FY 2026 and \$32,000 each year thereafter:

FY 2026: 11.2 FTE and \$1,430,000 (GF-S)

FY 2027: 14.1 FTE and \$1,759,000,000 (Psilocybin Control and Regulation Account)

FY 2028 and ongoing: 14.3 FTE and \$1,785,000 (Psilocybin Control and Regulation Account)

POLICY & ENGAGEMENT

Sections 1, 6, 8, 12, 22 – 23, 25, 27, 29, 30, 38, 42, 63, 66 – 65, 72, 95 – 96, 99, 102, 104, 106, 108, 111, 114, 124: The department will hire new staff to lead the policy, community engagement, and communication work required of this bill. Staff will support the board, provide policy support for rulemaking, manage ongoing rules updates, support program implementation, compliance, and licensing, publish and distribute information and research on psilocybin, coordinate with LCB and AGR, draft and publish materials for the public, maintain the program website, and conduct ongoing public outreach and community engagement:

- Policy and Engagement Manager 1.0 FTE
- Policy Analyst 1.0 FTE
- Community Engagement Specialist 1.0 FTE
- Communications Consultant 1.0 FTE
- Advisory Board Support 1.0 FTE

The Assistant Attorney General will provide legal advice implementation of the legislation and ongoing interpretation of the governing statutes. Attorney General Office charges will be \$2,000 in FY 2024, \$15,000 in each year thereafter.

Costs include staff and associated costs (goods and services, IT equipment, intra-agency, and indirect charges), and Assistant Attorney General services in the amount of 2,000 in FY 2024 and \$15,000 in each year thereafter:

FY 2024: 5.3 FTE and \$667,000 (GF-S)

FY 2025: 7.1 FTE and \$908,000 (GF-S)

FY 2026: 7.1 FTE and \$908,000 (GF-S)

FY 2027 and ongoing: 7.1 FTE and \$908,000 (Psilocybin Control and Regulation Account)

PROGRAM OPERATIONS & ADMINISTRATION:

Sections 8, 12, 22, 23, 25, 27, 63, 66, 72, 96, 99, 102 111, 114, 124: The department will hire new staff to lead the operations and administrative work required to administer this bill. This additional staff will direct and provide administrative support for the work of the policy and engagement, licensing, and compliance teams, review the scientific literature on psilocybin safety and efficacy, manage budgets and fiscal work, perform fee studies for the new credentials and ensure fees collected do not exceed the cost of administering this chapter, and perform fund management for the new Psilocybin Control and Regulation Account:

- Office Director 1.0 FTE
- Administrative Assistant 1.0 FTE
- Fiscal Analyst 1.0 FTE
- Science Officer 1.0 FTE

Costs include staff and associated costs (goods and services, IT equipment, intra-agency, and indirect charges):

FY 2024: 4.2 FTE and \$546,000 (GF-S)

FY 2025: 5.7 FTE and \$732,000 (GF-S)

FY 2026: 5.7 FTE and \$732,000 (GF-S)

FY 2027 and ongoing: 5.7 FTE and \$732,000 (Psilocybin Control and Regulation Account)

SOCIAL OPPORTUNITY PROGRAM:

Sections 114 & 124: The bill requires the department to create and administer a social opportunity program and allows the department to provide reduced license fees for social opportunity applicants at discounted rates, however the discounts may not increase the fee level borne by other applicants. The department assumes it will receive ongoing GF-S funding to pay the difference between the full rates and the discounted rates in order to achieve full cost recovery for the psilocybin regulatory program.

The qualifications for the social opportunity program and the actual discounted rates for those who qualify will be established in rulemaking. Because this will require extensive community engagement and costs will be contingent on many factors which are unknown at this point, the fiscal impact for the social opportunity program is INDETERMINATE.

PRODUCT TRACKING SYSTEM:

Section 42: The department believes an information technology system is necessary to fulfill the bill's requirements to track the movement of psilocybin products from the point of manufacture to the point of administration to a client, prevent diversion and product tampering, and assure compliance with the law. It is also necessary to meet reasonable public expectation for timely provision of records and information.

The bill allows use of the LCB cannabis product tracking system, but LCB has determined that their system is not suitable for this purpose. Therefore, the department assumes it will need to develop business requirements for a psilocybin tracking system, conduct a competitive procurement process, and implement a new system. The department assumes this will be a full competitive procurement and implementation project under oversight by the Washington State Office of the Chief Information Officer (OCIO).

The department assumes project staff will begin gathering business requirements and developing a Request for Information and a Request for Proposals during the program development and rulemaking period. Once rules are adopted and business requirements are complete, it will take the department 3 years to complete the vendor selection and system development process. The department's current Medical Cannabis Registry replacement project was used to estimate the costs for the psilocybin tracking system, with an assumption that the number of use cases for psilocybin product tracking will be double that of the Medical Cannabis Registry. Additionally, this technology solution will support a newly formed program and book of business for the department, whereas the Medical Cannabis Registry replacement project has benefitted from several years of lessons learned with the program's current technology vendor.

Project staff will be required to develop business requirements, manage the project, and serve as technical subject matter experts:

- Project Director 1.0 FTE
- Business Project Manager 1.0 FTE
- IT Project Manager 1.0 FTE
- IT Business Analysts 2.0 FTE
- IT Testing 2.0 FTE
- Development 2.0 FTE
- Business Subject Matter Expert 1.0 FTE
- Existing HTS Staff Support 0.3 FTE
- o Enterprise Architect
- o Data Services
- o Portfolio Manager
- o Information Security
- o Server & Network Operations
- o Records Management

Additionally, the project will require contracted outside expertise and support as required by OCIO:

- Project Quality Assurance (\$540,000)
- Organizational Change Management (\$360,000)
- Attorney General Technology Acquisition (\$50,000)

Based on other system deployments, one-time vendor development costs are estimated at \$5,000,000 and ongoing annual licensing is estimated at \$1,500,000 each year.

The department assumes 1.0 FTE ongoing for a System Owner to manage the contract with the vendor, change requests, and configuration.

Costs include staff, associated costs (goods and services, IT equipment, intra-agency, and indirect charges), contracted support, and vendor development costs:

FY 2024: 1.5 FTE and \$209,000 (GF-S)

FY 2025: 7.2 FTE and \$1,031,000 (GF-S)

FY 2026: 15.1 FTE and \$2,268,000 (GF-S)

FY 2027: 15.3 FTE and \$3,989,000 (GF-S)

FY 2028: 15.3 FTE and \$4,020,000 (GF-S)

TOTAL COSTS TO IMPLEMENT THIS BILL:

FY 2024: 14.7 FTE and \$2,003,000 (GF-S)

FY 2025: 32.7 FTE and \$4,433,000 (GF-S)

FY 2026: 50.0 FTE and \$6,692,000 (GF-S)

FY 2027: 51.7 FTE and \$8,520,000 (GF-S: \$3,989,000; Psilocybin Control and Regulation Account: \$4,531,000) FY 2028: 51.2 FTE and \$8,511,000 (GF-S: \$4,020,000; Psilocybin Control and Regulation Account: \$4,491,000)

FY 2029: 43.1 FTE and \$8,811,000 (GF-S: \$2,441,000; Psilocybin Control and Regulation Account: \$6,370,000)

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

Account	Account Title	Type	FY 2024	FY 2025	2023-25	2025-27	2027-29
001-1	General Fund	State	2,003,000	4,433,000	6,436,000	10,681,000	6,461,000
NEW-1	Psilocybin Control and Regulation Account	State	0	0	0	4,531,000	10,861,000
		Total \$	2,003,000	4,433,000	6,436,000	15,212,000	17,322,000

III. B - Expenditures by Object Or Purpose

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	16.2	33.4	24.8	50.3	46.7
A-Salaries and Wages	1,243,000	2,814,000	4,057,000	8,785,000	7,843,000
B-Employee Benefits	457,000	1,026,000	1,483,000	3,198,000	2,907,000
C-Professional Service Contracts	59,000	139,000	198,000	2,054,000	3,969,000
E-Goods and Other Services	119,000	233,000	352,000	571,000	2,079,000
G-Travel	6,000	8,000	14,000		
J-Capital Outlays	40,000	39,000	79,000	62,000	44,000
T-Intra-Agency Reimbursements	79,000	174,000	253,000	542,000	480,000
Total \$	2,003,000	4,433,000	6,436,000	15,212,000	17,322,000

III. C - Operating FTE Detail: List FTEs by classification and corresponding annual compensation. Totals need to agree with total FTEs in Part I and Part IIIA

Job Classification	Salary	FY 2024	FY 2025	2023-25	2025-27	2027-29
ADMINISTRATIVE ASST 4	58,704	0.8	1.0	0.9	1.1	1.2
COMMUNICATIONS	87,144	0.8	1.0	0.9	1.1	1.1
CONSULTANT 5						
EPIDEMIOLOGIST 3	108,804	0.8	1.0	0.9	1.0	1.0
(NON-MEDICAL)						
Fiscal Analyst 2	53,000	2.6	5.9	4.3	9.2	9.4
FORMS & RECORDS ANALYST 1	45,852				0.4	0.3
HEALTH CARE INVESTIGATOR 3	78,900				0.3	0.5
HEALTH SERVICES CONSULTAN	55,872				0.9	1.1
1						
HEALTH SERVICES CONSULTAN	66,420		2.0	1.0	2.4	2.4
2						
HEALTH SERVICES CONSULTAN	75,120				0.5	0.6
3						
HEALTH SERVICES CONSULTAN	82,896	3.9	8.3	6.1	12.3	11.7
4						
Health Svcs Conslt 1	53,000	1.7	3.7	2.7	5.8	5.9
HEARINGS EXAMINER 3	96,156				0.1	0.2
IT APPLICATION DEVELOPMENT	115,824		0.3	0.2	1.1	0.6
SENIOR/SPECIALIST						
IT BUSINESS ANALYST - JOURNI	100,032	1.2	1.0	1.1	0.6	0.2
IT BUSINESS ANALYST -	110,292	1.0	2.0	1.5	2.0	1.2
SENIOR/SPECIALIST						
IT DATA MANAGEMENT -	110,292		0.5	0.3	2.2	1.3
SENIOR/SPECIALIST						
IT SYSTEM ADMINISTRATION -	105,060				0.2	0.1
JOURNEY						
MANAGEMENT ANALYST 5	91,524	1.3	2.0	1.7	1.2	1.1
TOXICOLOGIST 3	103,572	0.5	0.2	0.4	1.0	1.0
WMS02	114,360	0.8	3.0	1.9	5.2	4.5
WMS03	129,336	0.8	1.5	1.2	2.0	1.7
Total FTEs		16.2	33.4	24.8	50.3	46.7

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

Sections 1, 6, 8, 12, 22, 23, 25, 27, 29, 30, 38, 42, 63, 65, 95, 96, 99, 104, 106, 108, 114: The department will adopt a new chapter of rules in Title 246 WAC as necessary to implement this bill.

Section 117: The Pharmacy Quality Assurance Commission will adopt rules in WAC 246-945-040 as necessary to implement this bill.

Individual State Agency Fiscal Note

Bill Number: 5263 SB	Title: Psilocybin	Agency:	495-Department of Agricultur
Part I: Estimates	•	<u>, </u>	
No Fiscal Impact			
Estimated Cash Receipts to:			
NONE			
Estimated Operating Expendi	tures from:		
	-zero but indeterminate cost and/or sa	avings. Please see discussion.	
Estimated Capital Budget Imp	eact:		
NONE			
The cash receipts and expendity and alternate ranges (if approp.	ure estimates on this page represent the most riate), are explained in Part II.	likely fiscal impact. Factors impacting to	he precision of these estimates,
Check applicable boxes and f	follow corresponding instructions:		
X If fiscal impact is greater form Parts I-V.	than \$50,000 per fiscal year in the curre	ent biennium or in subsequent biennia	, complete entire fiscal note
If fiscal impact is less that	an \$50,000 per fiscal year in the current	biennium or in subsequent biennia, co	omplete this page only (Part I)
Capital budget impact, co	omplete Part IV		
	•		
Requires new rule makin	g, complete Part V.		
Legislative Contact: Mattl	new Shepard-Koningsor	Phone: 360-786-7627	Date: 01/11/2023
Agency Preparation: Kelly	McLain	Phone: 360-902-1945	Date: 01/16/2023
Agency Approval: Jeann	nie Brown	Phone: 360-902-1989	Date: 01/16/2023
OFM Paviany Mattl	navy Huntar	Phone: (360) 520 7078	Date: 01/26/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

SB 5263 would provide legal clinical access to psilocybin in a guided space with a clinical professional for adults. The program would start as a 2 year pilot, with primary regulatory authority for all components of the program given to the Department of Health (DOH). In this bill, the Department of Health is given the authority to direct the WSDA in whatever way they see fit to establish the program.

While psilocybin is not technically a plant, it is a fungi, and it is grown and consumed, and often (but not always) considered agricultural in nature. There would be a fiscal impact to WSDA if DOH asks WSDA to play a role in the licensing or testing or lab accreditations that impacted manufacturers, however, at this time, it is not clear what WSDA's responsibilities might be and what work would be assigned to the agency. Therefore, the fiscal impact of this bill at this time is indeterminate.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

No cash receipt impacts for WSDA.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

SB 5263 would provide legal clinical access to psilocybin in a guided space with a clinical professional for adults. The program would start as a 2 year pilot, with primary regulatory authority for all components of the program given to the Department of Health. The Department of Health is given the authority to direct the WSDA in whatever way they see fit to establish the program.

While psilocybin is not technically a plant, it is a fungi, and it is grown and consumed, and often (but not always) considered agricultural in nature. There would be a fiscal impact to WSDA if DOH asks WSDA to play a role in the licensing or testing or lab accreditations that impacted manufacturers, however, at this time, it is not clear what WSDA's responsibilities might be and what work would be assigned to the agency. Therefore, the fiscal impact of this bill at this time is indeterminate.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

Non-zero but indeterminate cost and/or savings. Please see discussion.

III. B - Expenditures by Object Or Purpose

Non-zero but indeterminate cost and/or savings. Please see discussion.

III. C - Operating FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part I and Part IIIA.

NONE

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

 $Acquisition\ and\ construction\ costs\ not\ reflected\ elsewhere\ on\ the\ fiscal\ note\ and\ description\ of\ potential\ financing\ methods.$

NONE

IV. D - Capital FTE Detail: FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.

NONE

No capital impacts for WSDA.

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.