



# PSILOCYBIN WORKGROUP MEETING

December 2, 2022



# *Health*

*Where Equity, Innovation, & Engagement meet.*

We hope that together we will not just move forward, but **we will thrive and transform** our health system in Washington and **be a model for others** — where together we create the reality that **everyone across Washington can live the healthiest of lives**. The work has only just begun; this moment marks the beginning of this road.

WASHINGTON STATE DEPARTMENT OF HEALTH  
**TRANSFORMATIONAL PLAN**  
A VISION FOR HEALTH IN WASHINGTON STATE



**CORNERSTONE VALUES:** EQUITY • INNOVATION • ENGAGEMENT  
**VISION:** EQUITY AND OPTIMAL HEALTH FOR ALL

WASHINGTON STATE DEPARTMENT OF HEALTH  
**TRANSFORMATIONAL PLAN**  
A VISION FOR HEALTH IN WASHINGTON STATE

**Scan QR Code to read about the Department of Health's  
Transformational Plan**



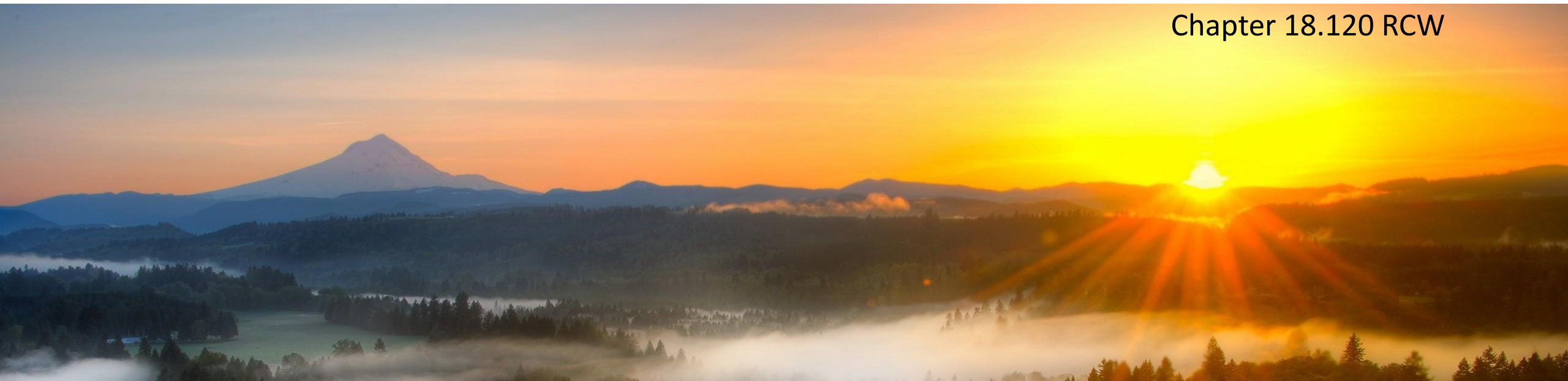
# Existing Regulatory Framework for Health Care in Washington and DOH's Role



# When Should a Health Profession Be Regulated?

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public,
- The potential for harm is easily recognizable and not remote,
- The public will benefit from an assurance of professional ability, and
- There is no other, more cost-effective means of protecting the public.

Chapter 18.120 RCW



# Title 18 RCW – Businesses and Professions

## Legislature

- Establishes the regulatory authority for the profession (the body that sets rules and can take disciplinary action on a license)
- Sets the scope of practice (broadly, what licensees are allowed to do)
- Creates general requirements for licensure

## DOH, Boards, Commissions

- Set additional, more specific licensure requirements in rule:
  - Education and training
  - Testing
  - Supervised experience
  - Continuing education
  - Health and safety standards
  - Policies and procedures

# Health Care Regulators

## DOH



Emergency medical technicians  
Home care aides  
Mental health counselors  
Social workers  
Substance use disorder professionals



Hospitals  
Ambulatory Surgery Centers  
Behavioral Health Agencies  
Residential Treatment  
Medical Test Sites  
Home Care and Hospice

## Boards and Commissions



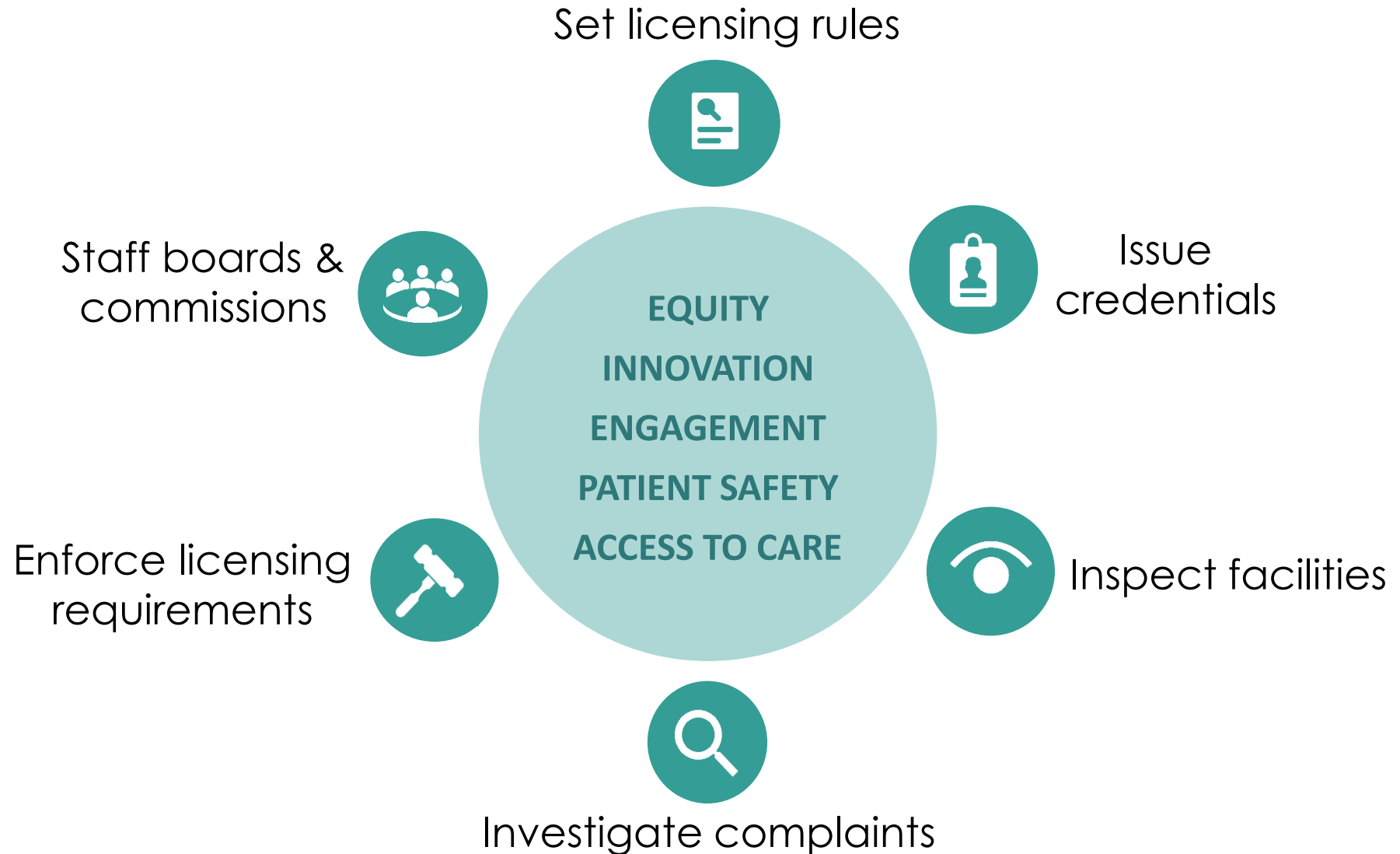
Dentists  
Nurses  
Physical therapists  
Physicians (MD, DO, ND)  
Psychologists  
Pharmacists



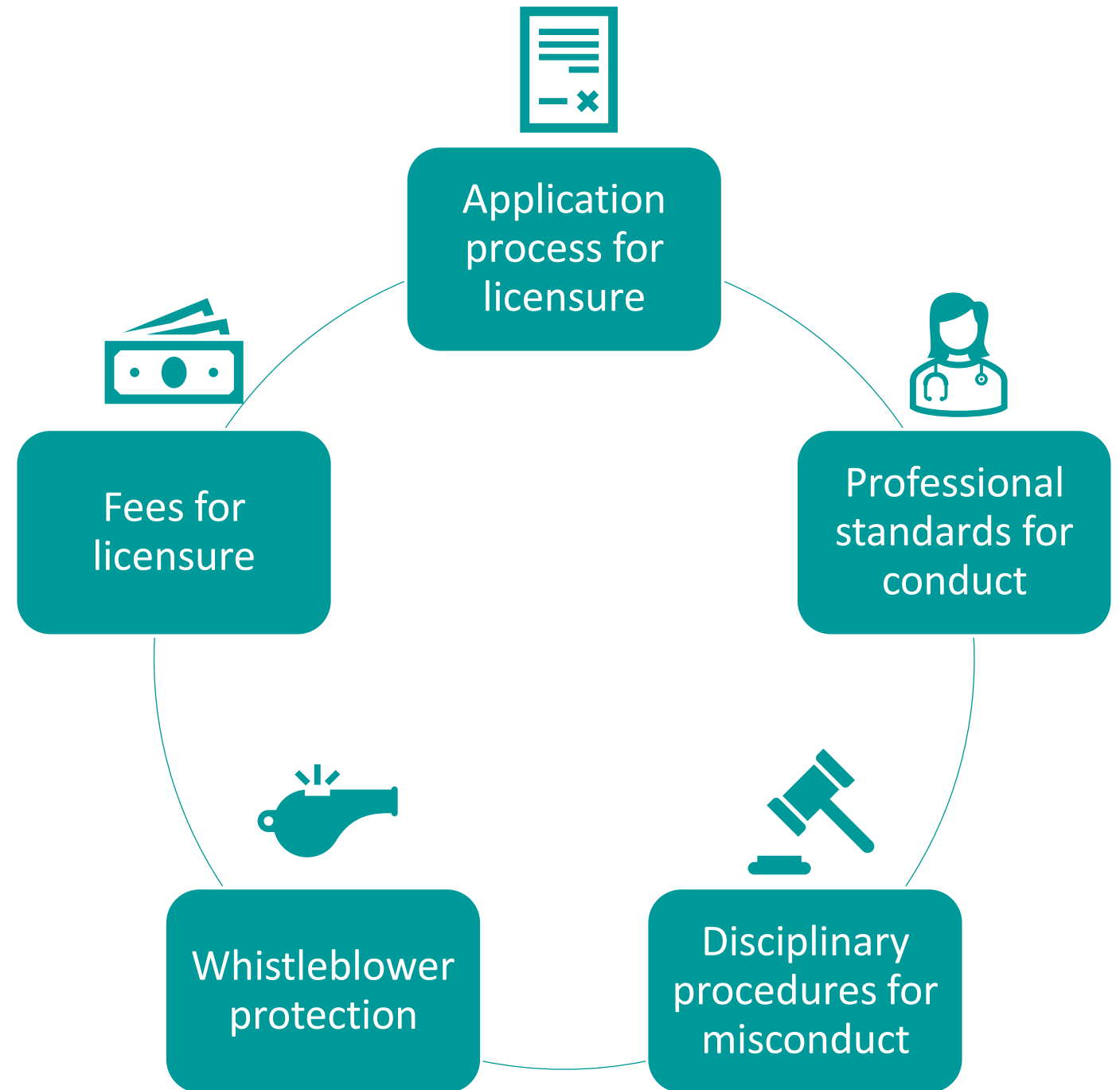
Pharmacies



# Health Care Regulation in DOH



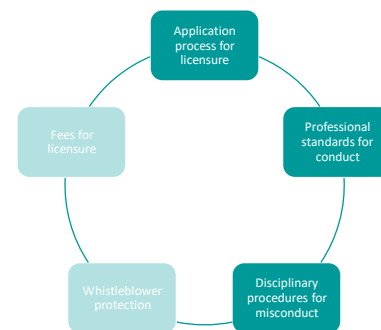
All health care professionals regulated under Title 18 are subject to a **common set of laws** in addition to profession-specific practice acts.



# The Uniform Disciplinary Act (UDA)

## Chapter 18.130 RCW

- Provides a common set of professional standards for practice
- Provides standardized procedures for licensing and disciplining all health professionals in Washington
- Applies to all health professions under Title 18, regardless of whether the regulatory authority is DOH or a board or commission
- Legislative intent: UDA should cover all health and health-related professions newly regulated by the state





# UDA – Authority of DOH, Boards, Commissions

- Grant or deny license applications
- Restrict or place conditions on a license of new licensees
- Investigate complaints of unprofessional conduct; review and audit records
- Hold hearings, issue subpoenas, take depositions, compel attendance at hearings
- Impose sanctions, issue citations, assess fines, revoke a license
- Order summary suspension or restriction of a license when there is an immediate threat to public health and safety



# UDA – Application Review

- Does the applicant have a criminal history that would pose risk to patients?
  - State (WSP) and federal (FBI) background checks
  - No disqualifying crimes list
  - Each application assessed individually, taking into consideration the applicant's past crimes and the type of license they are applying for
- Can the applicant practice with reasonable skill and safety?
  - Self-reported health conditions
  - Voluntary substance use monitoring programs



# UDA – Examples of Professional Misconduct

- Violating any state or federal law regulating the profession
- Engaging in dishonest acts, corruption, fraud, misrepresentation
- Obtaining a license through false or misleading statements
- Aiding or abetting unlicensed practice
- Providing neglectful or poor-quality care that results in injury or unreasonable risk of harm
- Failing to cooperate or comply with an order
- Practicing beyond the allowed scope





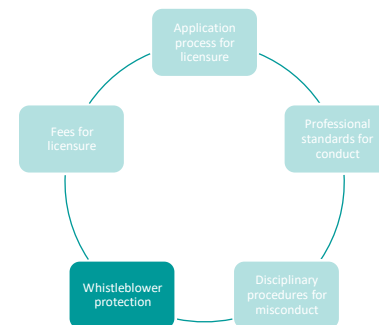
# UDA – Examples of Professional Misconduct

- Failing to adequately supervise staff
- Being convicted of a gross misdemeanor or felony related to practice of the profession
- Possessing, using, or prescribing drugs other than for legitimate purposes or violating any drug law
- Allowing drugs to be unlawfully removed from a facility or shared, or prescribing for oneself
- Current misuse of alcohol, controlled substances, legend drugs
- Abusing or engaging in sexual contact with a patient or client



# Whistleblower Protection

- RCW 43.70.075
  - Protects confidentiality of whistleblowers who make complaints to DOH against health care professionals and facilities
  - Provides a right to civil action to whistleblowers who are subjected to retaliatory action
- Chapter 49.60 RCW (Human Rights Commission)
  - Provides remedies for employees who are subjected to retaliatory action for complaining against their employer



# Fees for Health Professions and Facilities

- State law requires the regulation of health professions and facilities to be supported by fees paid by licensees (RCW 43.70.250)
- Fees from one profession may not be applied to regulating any other profession
- In very limited cases, the legislature has chosen to provide funding to offset licensing costs (e.g., midwives, emergency medical professionals)





# Fees for Health Professions and Facilities

- DOH is obligated to charge fees that allow us to recover the costs associated with regulating each profession
- What is cost recovery?
  - Off-set expenditures for rulemaking, licensure, complaint investigation, discipline
  - Maintain a sufficient financial reserve to cover fluctuations in expenditures (e.g., a very expensive disciplinary case)



# Role of the Pharmacy Quality Assurance Commission in Drug Regulation

# Pharmacy Quality Assurance Commission Role

- The commission regulates the practice of pharmacy and the dispensing, distribution, wholesaling, and manufacturing of all controlled and non-controlled substances, including psilocybin (exception is cannabis)
- Controlled substances are listed in drug schedules in chapter 69.50 RCW, chapter 246-945 WAC (commission's rules), and in the DEA's drug schedules (21 CFR §1308)
  - Pharmacy commission licensees must follow WA state law, the commission's rules, and the DEA's rules
  - Controlled substances necessitate registration with both the DEA and PQAC, unless an exemption is otherwise met

# Pharmacy Commission Role, continued

- "Manufacture" in RCW 18.64.011(21) includes the "production, preparation, propagation, compounding, or processing of a drug or other substance or device..."
  - Manufacturing in WA requires a manufacturer's license from PQAC (RCW 18.64.045)
  - All manufacturers in WA must adhere to the FDA's Current Good Manufacturing Practice (CGMP) (WAC 246-945-550)
- Other activities that require registration with PQAC
  - Research with controlled substances, analytical labs, animal related drug control

# DOH Responsibilities Under SB 5660 and Ability to Implement

# SB 5660 – DOH Responsibilities

- Establish a psilocybin advisory board with >20 appointed members to advise DOH
- Conduct rulemaking, license, and regulate:
  - Psilocybin manufacturers, service centers, and facilitators
  - Employees of manufacturers and service centers
  - Laboratories that test psilocybin products
- Create a social opportunity program for the psilocybin industry to aid people from distressed areas through reductions in fees
- Develop and maintain a system for tracking transfer of products or use LCB's
- Publish research and information on safety and efficacy of psilocybin
- Develop a hotline/website to answer questions about licensed premises



# DOH Expertise and Capacity to Implement

- Standing up psilocybin services involves novel work for DOH such as a social opportunity program for fees and regulation of a cultivated product
- The proposed regulatory structure is highly complex
- The proposed regulatory structure has some similarities to existing laws for other health professions (e.g., Uniform Disciplinary Act), but it is distinct and will require extensive rule-making, procedure development, and IT system changes
- Can DOH implement SB 5660? **Yes**, if appropriately resourced and with more time

# Timeframe to Implement

- Two to three years
- Why?
  - Staff must be hired (approximately 30 FTE)
  - Advisory board needs to be established
  - Many complex rules need to be developed by on new concepts and in an equitable manner that allows broad community engagement
  - Social Opportunity Program must be developed – method for identifying distressed communities, fiscal analysis of tiered fees
  - Psilocybin tracking system must be acquired and implemented

# Additional Considerations

- Social opportunity program
  - Intriguing concept for addressing equity in a regulatory structure
  - Reduced fees for licensees from distressed communities means higher fees for licensees from non-distressed communities
  - DOH must recover the full cost of the psilocybin regulatory program unless the legislature chooses to offset the cost
- System for tracking transfer of psilocybin product
  - Acquiring a new system for this purpose would be expensive and take several years
  - Adapting an existing system (e.g., LCB's) is the more cost-effective approach

# Additional Considerations

- Psilocybin Advisory Board
  - DOH has authority for rules and enforcement; Advisory Board is advisory even though it has requirements similar to a Class 1 board
  - DOH must follow the Administrative Procedures Act when rule-making which requires seeking broad public input and engagement beyond the Advisory Board
- Regulation of health care providers that participate
  - Regulatory authorities (DOH, board, commissions) have a duty to consider disciplinary action when they become aware that a licensee is engaging in illegal activity on any level – local, state, or federal
  - As long as psilocybin remains federally illegal, boards and commissions will be challenged to fulfill their duty regardless of state law

# Recommendation

- Consider using the regulatory framework for health care in Washington (e.g., Uniform Disciplinary Act) to minimize implementation timeframe

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