

**Subcommittee: Public Health and Health Equity**  
**Prioritized Questions**  
**(Questions to address organized in order of priority 1,2,5,6,4,3,7)**

---

**Priority Question #1**

- How will “health equity” be defined in this specific space under the Natural Medicine Health Act?
  - Who is this area’s core audience?
- Motion Adopted Health Equity Definition
  - **“Health Equity” is Defined as** - Health equity is both an outcome and a process. Health equity happens when everyone has an equal opportunity to be as healthy as they can be. No one's race, ethnicity, disability, age, sexual orientation, gender identity, socioeconomic status, geography, or preferred language should negatively affect their health care. Health equity work includes removing obstacles to positive health outcomes, such as healthcare access barriers.

**Priority Question #2**

What are the greatest barriers to ensuring health equity?

- ... as it relates to the public accessing natural medicine services?
- ... as it relates to licensing product cultivation and testing, healing centers, and facilitators?
- How do we support marginalized populations in obtaining licenses and succeeding in the cultivation, facilitation, and healing center arenas?
- Equity for cost - How do we ensure the cost of the medicine and the cost of the prescription are equitable and reasonable?

**Priority Question #3**

- What measures can be taken to ensure equitable access to natural medicine therapy?
  - What measures can be taken to promote public and private health insurance coverage of natural medicine services?
  - What are the pathways to coverage by the state Medicaid program? Medicare? Veterans Health Administration? Tricare? Indian Health Service?
  - Is it possible to promote coverage of natural medicine services as an add-on to existing covered services?
  - How do we ensure the affordability of natural medicine services?
  - How can we support access to natural medicine services for the uninsured and underinsured?

**Priority Question #4**

- How will this relate to insurance for those participating in the delivery of natural medicine services?
  - For cultivators? Facilitators? Healing centers?
  - How does this relate to malpractice coverage?
  - How can we ensure these participants in the process can obtain the insurance they need to operate?

**Priority Question #5**

- What educational materials about natural medicine and natural medicine services should be disseminated to the public?
  - What would the scope of content for public education look like?
  - What is the timing of these public education campaigns?
  - What mediums should be used to disseminate this information?
  - How do we ensure cultural appropriateness and language accessibility?

**Priority Question #6**

- What education should be provided to cultivators and testers, healing centers, and facilitators as it relates to health equity?
  - What core competencies need to be identified to ensure equity is applied in this framework?

**Priority Question #7**

- How will those participating in the delivery of natural medicine services process payment? Will they be able to access banking services?

## **Subcommittee: Indigenous and Religious Use and Outreach**

### **Prioritized Questions**

---

#### **Priority Question #1**

- How do we define “indigenous use” within the confines of the law?

#### **Priority Question #2**

- How do we define “religious and spiritual use” within the confines of the law?
  - What are the distinctions between “religious use” and “spiritual use”?

#### **Priority Question #3**

- What are the distinctions between “religious use” and “spiritual use”?

#### **Priority Question #4**

- What specific communities that fit the definition of an indigenous community and a religious community do we need to engage?

#### **Priority Question #5**

- Who is this area’s core audience?

#### **Priority Question #6**

- What are the primary trusted research resources related to the efficacy of psilocybin, including cultural responsibility?

#### **Priority Question #7**

- What will be the outreach strategies to indigenous communities?

#### **Priority Question #8**

- What will be the outreach strategies to religious and spiritual communities?

#### **Priority Question #9**

- How can indigenous wisdom and tradition provide guidance to Coloradans’ allowable use of natural medicine?

#### **Priority Question #10**

- What are the standards that have been set by historical/generational precedence?

#### **Priority Question #11**

- What are the primary trusted resources around Psilocybin, and what cultural responsibility is around it?

#### **Priority Question #12**

- What are the existing barriers to indigenous use and religious use access?

#### **Priority Question #13**

- What does the “sharing of benefits” look like in relation to healing centers?

#### **Priority Question #14**

- Inform communities of different modalities and treatments?

#### **Priority Question #15**

- What education should be provided to facilitators as it relates to indigenous use?

#### **Priority Question #16**

- What education should be provided to facilitators as it relates to spiritual and religious use?

## **Prioritized Questions to Address**

### **Subcommittee: Harm Reduction and Public Safety**

---

1. What are the primary trusted research resources related to the efficacy of psilocybin, including harm reduction?
  - a. What labeling should be provided to the participant to know the dosage and other needed disclosures?
2. What is the appropriate time frame between sessions?
3. What disclosures of regulation should be provided to the participant so they understand their rights under the law?
4. What are the recordkeeping responsibilities of the healing centers, including as it relates to third-party accessibility (i.e., selling to or voluntary use in research)?
5. What labeling should be provided to the participant to know the dosage and other needed disclosures?
  - a. What labeling and packaging?
6. What other health and safety warnings must be provided to participants before psilocybin is administered?
7. What enforcement mechanisms should be in place to ensure participant safety is ensured?
  - a. How do patients/clients know how to file complaints and raise concerns/grievances?
8. What education should be provided to facilitators as it relates to harm reduction and public safety?
9. Who is this area's core audience? What is the core messaging?
10. Bounds of appropriate physical contact, what is consent around physical, what is informed physical consent?
11. What required documents must licensed facilitators provide prior to a session? What are the resources on the document?
12. What are labeling and packaging requirements?
  - a. How do we ensure the package and labeling is clear?
  - b. What will be physically on the product?
  - c. How do we ensure Psilocybin is readily identifiable outside of packaging?
13. Can we create a training curriculum on Harm Reduction for EMS and law enforcement?

## **Prioritized Categories**

Record Keeping

Provisional

Advertising and Disclosures

Education and Training

### **Recordkeeping**

- What disclosures of regulation should be provided to the participant so they understand their rights under the law?
- What are the recordkeeping responsibilities of the healing centers, including as it relates to third-party accessibility (i.e., selling to or voluntary use in research)?
- What required documents must licensed facilitators provide prior to a session? What are the resources on the document?
- What enforcement mechanisms should be in place to ensure participant safety is ensured?
  - How do patients/clients know how to file complaints and raise concerns/grievances?

### **Provisional**

- What is the appropriate time frame between sessions?
- What other health and safety warnings must be provided to participants before psilocybin is administered?
- Bounds of appropriate physical contact, what is consent around physical, what is informed physical consent?
- How do patients/clients know how to file complaints and raise concerns/grievances?

### **Advertising and Disclosures**

- What labeling should be provided to the participant to know the dosage and other needed disclosures?
  - What labeling and packaging?
- Who is this area's core audience? What is the core messaging?
- What are labeling and packaging requirements?
  - How do we ensure the package and labeling is clear?
  - What will be physically on the product?
  - How do we ensure Psilocybin is readily identifiable outside of packaging?
- What enforcement mechanisms should be in place to ensure participant safety is ensured?
  - How do patients/clients know how to file complaints and raise concerns/grievances?

### **Education and Training**

- Who is this area's core audience? What is the core messaging?
- What are the primary trusted research resources related to the efficacy of psilocybin, including harm reduction?
  - What labeling should be provided to the participant to know the dosage and other needed disclosures?
- What labeling should be provided to the participant to know the dosage and other needed disclosures?
  - What labeling and packaging?
- What enforcement mechanisms should be in place to ensure participant safety is ensured?
  - How do patients/clients know how to file complaints and raise concerns/grievances?
- What education should be provided to facilitators as it relates to harm reduction and public safety?

## Prioritized Questions

---

### **Priority Question #1**

- Can we create a training curriculum on Harm Reduction for EMS and law enforcement?

### **Priority Question #2**

- What are labeling and packaging requirements?
  - How do we ensure the package and labeling is clear?
  - What will be physically on the product?
  - How do we ensure Psilocybin is readily identifiable outside of packaging?
  - What labeling should be provided to the participant to know the dosage and other needed disclosures?
  - What labeling and packaging?
  - Include QR code for the full extent of labels
  - Child-resistant packaging
    - Industry Standard and Global, international standard

### **Priority Question #3**

- Who is this area's core audience? What is the core messaging?
  - Providers?
  - 1. Patient and Consumer
  - 2. Psychedelic Curious Patient
  - Psychedelic curious community
  - Spiritual community
  - Religious community
  - 3. Practitioner therapists
  - 4. EMS LE
  - 5. Mental Health Community

## **Subcommittee: Products, Research, and Data**

### **Prioritized Questions (Strategic Work Plan)**

---

#### **Production, Testing, Distribution, Administration, Data**

##### **Priority Subject #1**

###### **Production**

- What are the best practices for psilocybin production?
- What species of psilocybin?
  - Should a single species be selected? Do we allow for variability in strains?
- Acquire? Possess? Manufacture? Deliver? Supplies? Dispenses?
- What are the appropriate additives or adulterants that should be allowed? Which should be prohibited?
- What should be the requirements and standards for in-house testing of psilocybin for concentration and contaminants?
  - What are the proper protocols for the disposal of Psilocybin and any byproducts related to the production of Psilocybin?
- What are the regulations and standards around cultivation?
- What is the difference between cultivation and synthesis when considering the other natural medicine on the list?
- What are the security standards at facilities for production?
- What are the qualifications for testing and cultivation?
  - How does that impact the license?
  - Who polices the cultivation and testing facilities to ensure?

##### **Priority Subject #2**

###### **Cultivation**

- What are the regulations and standards around cultivation?
- What are the qualifications for testing and cultivation?
  - How does that impact the license?
  - Who polices the cultivation and testing facilities to ensure?
- What is the difference between cultivation and synthesis when considering the other natural medicine on the list?
- Do we allow for unrestricted cultivation of all biological genera containing psilocybin?
- What species of psilocybin?
  - Should a single species be selected? Do we allow for variability in strains?
- Cultivate? What are related supplies?
- What are the best practices for psilocybin cultivation?
- What are the appropriate additives or adulterants that should be allowed? Which should be prohibited?
- What should be the requirements and standards for in-house testing of psilocybin for concentration and contaminants?
- How do you dispose of psilocybin, including that which has failed testing or has been improperly stored?
- What are the security standards at cultivation facilities?

### **Priority Subject #3**

#### **Testing**

- What are the qualifications for testing and cultivation? (Overlap with Priority Subject#2)
- How do we test the potency of natural materials?
- How do we ensure all labs are using validated potency testing?
  - What outcomes are required for proficiency testing?
  - Should testing labs be subject to a round-robin of potency testing for the eligibility of their licenses?
- What should be the requirements and standard for independent testing of psilocybin for concentration and contaminants?
- What are the security standards at facilities for Testing?

### **Priority Subject #4**

#### **Distribution**

- How do we ensure the safe Transfer and Transportation of Natural Medicine?
- How do we ensure that Natural Medicine is Secure and Safely transported?
- What are the regulations and standards around distribution?
- What are the security standards at facilities for distribution?

### **Priority Subject #5**

#### **Administration**

- What are tools that facilitators will use to identify if psilocybin would be beneficial to a potential participant?
- What are the potential health risks, and how should they be disclosed to a potential participant?
- What are the best practices for dose control?
- What should the dosage be for this facilitation?
  - What does existing evidence suggest about dose control?
  - What are the methods of administration?
- Are there circumstances in which psilocybin should be denied to a participant?
  - How do different methods of administration impact dosage control and the methods of administration?
  - Is there a mechanism for addressing adverse events? And how are we tracking?
- How do you dispose of psilocybin, including that which has failed testing or has been improperly stored?
- What education should be provided to facilitators as it relates to products, research, and data?
- What are existing resources on dosage control?
  - Identify the regiment for specific diagnoses.
- What are the security standards at facilities for Administration?



## Priority Subject #5

### Data

- How do we ensure public transparency for those licensees involved in one or more aspects?
- What, if any, information should be reported by licensed facilitators to the state to promote a balanced regulatory environment?
- What data should be collected?
- How can data be used to promote safety, effectiveness & Equity?
- What are the primary trusted research resources related to the efficacy of psilocybin, including product safety?
- How do we build a state-wide registry to capture adverse events?
- How do we make the data program optional?
- How do we remove PHI?
  - How do we protect patient confidentiality?
- What Data is Mandatory?
- What does a robust data registry look like?
- What type of registry is it?
- What program analysis can we conduct?
- How do we ensure data is safe? And not subject to HIPPA
- How is the program's effectiveness evaluated?
- What rules existed regarding access to data in the State of Colorado?
- How do we make data collection user-friendly so as not to be a huge imposition?
- What is the purpose of the data, and what will it be used for?
- How does this become visible to the public and researchers?

## 5/11/23 Discussion Items

### Highest Priority from Production

1. Should a single species be selected? Availability of different strains
2. What are the best practices for psilocybin production?
  - a. Do we allow for unrestricted cultivation of all biological genera containing psilocybin?
3. Review best practices around Natural Psilocybin Cultivation.

## 5/24/23

### Starting Point

- What are the appropriate additives that should be allowed? Which should be prohibited?
  - Skippy - Allowances of additives within the products themselves. And the stacking of products
  - Skippy - two other components to it. Do we want things to be available? What products need to be added?
  - Sue - conflicted - could be treacherous - allowing materials to be encompassed with the products that are being approved.
  - Brad - additives at the time of production and cultivation
    - Cultivation - w/o research for additives, it could be dangerous
    - Additives at the cultivation stage.

## **Subcommittee - Qualifications, Licensing, and Training**

### **Prioritized Subjects and Questions**

---

#### **Priority Subject #1**

##### **Qualifications**

- What are the different levels (spheres) of Facilitators, and how are they evaluated?
  - 4-5 Spheres (Lightest Touch/Community Use with no diagnosis) (Pre and post-engagement)
  - What are the types of participants?
  - What are the types of treatments?
- How are legacy facilitators or curanderos/curanderas regulated?
  - How can these traditional facilitators be added in
- What should the baseline education requirements be for a facilitator? Should there be an on-the-job training option in place of the educational baseline?
- How should previous convictions and criminal history be taken into account?
- What qualifications are unique to facilitators?
- What are the questions for the experts?

#### **Priority Subject #2**

##### **Training**

- What should be the training requirements for facilitators?
  - How will we make training and licensing affordable and accessible?
  - What is the minimum clinical training in health and science?
  - What qualifications are unique to facilitators?
- What would the requirements be for approved training?
- What would the requirements be? And would trainers in those training programs need to be licensed facilitators?
- How do we require consistency in education?
- What should be the continuing education requirements for facilitators?
- What training should be provided to facilitators on contraindications, mental health, mental state, physical health, physical state, social and cultural considerations, physical environment, preparation, integration, transference, countertransference, and ethics?
- What should be the healing center's training requirements for non-facilitator staff?

### **Priority Subject #3**

#### **Licensing**

- How are legacy facilitators, curanderos/curanderas, regulated?
  - How can these traditional facilitators be considered when applying for a license?
- What should be the continuing education requirements for facilitators?
- What should be the licensing scheme for entities permitted to engage in the testing of psilocybin?

### **Priority Subject #4**

#### **Administration**

- How do you define a Preparation Session? Administration Session? Integration Session?
- What should be the role of the facilitator in the preparation session? In the administration session? In the integration session? What if there is more than one facilitator? Or if the participant changes consent between sessions?
  - Is the preparation session “meeting” in person, remotely, or either?
  - Is there a gap in time between the Preparation Session and the Administration Session? If so, how short or long should that be?
  - Is there a gap in time between the Administration Session and the Integration Session? If so, how short or long should that be?
- What qualifies as proper supervision during a Preparation Session? An Administration Session? An Integration Session?
- What qualifies as proper supervision for safe transportation for the participant when the session is complete?
  - What is the complaint procedure?
- What should be the provisions for group administration settings?

### **Priority Subjects #5**

#### **Record Keeping, Education, Public facing, Ethics**

- How do we ensure public transparency for those licensees involved in one or more aspects?
- What are the recordkeeping responsibilities of the healing centers, including as it relates to third-party accessibility (i.e., selling to or voluntary use in research)?
- Who is this area’s core audience? What is the core messaging?
- How do we address conflicts for individuals with multiple licenses?
- How do we rectify conflicts for people who hold multiple licenses?
- What qualifies as proper supervision for safe transportation for the participant when the session is complete?
  - What is the complaint procedure?

### **Priority Subjects #6**

#### **Affordability**

- How will we make training and licensing, affordable and accessible?

**Subcommittee: Emergency Response, Safety, and Ethics**  
**Prioritized Questions by Subject: Safety and Crisis Care, Documentation, and Education**

---

**SUBJECT #1**

**Safety and Crisis Care**

1. In times of emergency, should health centers/facilitators be required to provide emergency responder services with accurate composition and dosing information of psychedelic substances administered to clients?
2. What does a safety plan look like?
  - a. Where and when do you activate EMS?
  - b. What are EMS Agency guidelines for activation?
3. What ethical and safety considerations should be disclosed at the Preparation Session? Administration Session? Integration Session?
4. Under what circumstances can a facilitator or a healing center refuse to provide psilocybin to a participant?
5. What should be included in the Healing Centers Safety Plans/Security Requirements? How will they address how they are complying with security requirements, on-site cameras, managing firearms, prohibiting other substance use on-premises, etc.?
6. What should be in a transportation plan for a healing center?
7. What requirements should there be for crisis management? Who needs to be trained? How often?
8. What education should be provided to facilitators as it relates to emergency response, safety and ethics?
9. What disclosures of personal medical history (i.e current medications to consider contraindications and drug interactions) should be provided by the participant to the facilitator?
  - a. How should personal medication be verified?
  - b. What is the relationship between the primary care provider and the healing center?
  - c. Should there be a waiver of liability if there are interactions that the participant did not disclose?
  - d. What are the diagnostic contraindications, family history on medical health, and mental health disclosed?
10. What specifically should be on the form that each facilitator and participant must sign before providing and respectively receiving psilocybin verifying the participant has received information about identified risks and contraindications?
11. What are the standards necessary for Medical monitoring?
  - a. Do we want to monitor vital signs during administration?
12. What parameters need to be set up to avoid unprofessional conduct, such as sexual relationships?
  - a. What constitutes unprofessional conduct?
13. What should be the parameters for services provided in private residences?
  - a. How do you address the requisite of transportation plans if the facilitation is occurring in a private residence?
  - b. How do you address safety requirements in a private residence?
  - c. How do you address crisis response in a private residence?
  - d. Does informed consent look the same in a private residence?
14. What should be the requirements for mandated reporting? - CROSSOVER

15. What role (if any) does a Home Owners Association (HOA) play in the overall safety plan/approval of a healing center in a private residence in the community for which they are responsible?

## **SUBJECT #2**

### **Documentation**

16. What education and qualification disclosures should be provided to participants before the Preparation Session? Administration Session? Integration Session?
17. What should be the disclosure requirements if a facilitator holds another occupational license by the Department of Regulatory Agencies, particularly issued by a state healthcare board?
18. What impact will the use of Natural Medicines have on VA access to care?
- What information is disclosed in the preparation session?
  - What is recognized in a preparation session in regard to federal law?
19. What disclosures of personal medical history (i.e current medications to consider contraindications and drug interactions) should be provided by the participant to the facilitator?
- How should personal medication be verified?
  - What is the relationship between the primary care provider and the healing center?
  - Should there be a waiver of liability if there are interactions that the participant did not disclose?
  - What are the diagnostic contraindications, family history on medical health, and mental health disclosed?
20. Will participants be given confidentially by facilitators and healing centers? If so, what are the limits of confidentiality (if any)?
21. What is the process for informed consent? What is the timeline? Should it be given once or throughout various stages (preparation, administration, and integration)? If the latter, what will be the distinctions, if any?
22. What disclosures need to be provided to the participant about their anticipated experience (i.e. techniques, touching, etc.)
23. What should be allowed and prohibited for advertising and marketing of regulated psilocybin healing centers?
- Who is this area's core audience? What is the core messaging?
24. What parameters should be in place for those with multiple licenses or overlapping licenses under the statutory definition for the sake of public transparency?
25. What should be the requirements for mandated reporting to the Department of Human Services, county adult protective services, and child protective services?
26. What should be the requirements for mandated reporting? - (*crossover with safety and crisis care*)

## **SUBJECT #3**

### **Education**

27. What education and qualification disclosures should be provided to participants before the Preparation Session? Administration Session? Integration Session?
28. What core competencies need to be identified to ensure equity is applied in this framework?
29. What education should be provided to facilitators as it relates to emergency response, safety, and ethics?