Joe Lombardo *Governor*



DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIRECTOR'S OFFICE

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Richard Whitley, MS *Director*

Psychedelic Medicines Working Group Draft Meeting Minutes

DATE: Friday, October 11, 2024

TIME: 9:00 a.m. - Adjournment

VIDEO CONFERENCE:

https://teams.microsoft.com/l/meetup-

<u>join/19%3ameeting_ZTMzZWZmMjktNjlmMC00NDZkLTg5MjctOWMyN2EyMTFmYzEx%40thread.</u>

v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-

1544d2703980%22%2c%22Oid%22%3a%22f302c679-e632-4652-911c-95066f69c9a7%22%7d

TELECONFERENCE LINE: 1-775-321-6111

CONFERENCE ID: 172 799 042#

1. Call to Order

The meeting was called to order at 9:03 a.m. by Chair Marla McDade Williams.

2. Welcome and Introductions (Roll Call)

Members Present by Video: Marla McDade Williams, Terry Kerns, Mark McBride, Senator Rochelle Nguyen, Diane Goldstein, Assemblyman Max Carter, Jonathan Dalton, Dr. Mujeeb Shad, Burton Tabaac, Dustin Hines, Catherine Cotter, Joshua Garber, John Oceguera, Scott Killebrew (joined after roll call)

Members Absent: Assemblywoman Danielle Gallant

Public: Ayla Babakitis, Belz and Case Scribe, Elyse Monroy-Marsala, Emilie Dekker, Greg Bailor, JC, Jen G, Jennifer Isom, Lea Case, Lorey Bratten, Marina Rex, Nadine Kienhoefer

3. Public Comment

There was no public comment.

4. For Possible Action: Approval of June 25, 2024 and September 6, 2024 Meeting Minutes Marla McDade Williams asked members if there were any comments on the meeting minutes.

Comments/Questions:

Dr. Dustin Hines: Some of the science by Dr. Mujeeb Shad talking about toxicity got mislaid. Brian Lang corrected it later in the meeting. The record should not reflect misinformation. Scientifically it is not correct the way the record is right now. Dr. Mujeeb Shad claimed psilocybin is toxic. Maybe a scientific reference rather than just people talking that show the facts. Also, maybe Brian Lang's comment with citing the actual paper.

Dr. Mujeeb Shad: Commented did not state psilocybin is toxic. Someone asked about the higher dosages. Trip dosages there is much less data for safety and that is what he was talking about. Micro dosages are completely safe as has been shown by multiple studies.

Mark McBride: Conversation back and forth should stay in the minutes.

Jonathan Dalton: The June 25th draft minutes state various links posted in the chat for reference. Requested access to the chat history.

Diane Goldstein: Make sure research is properly cited in the minutes or in the draft report.

Senator Rochelle Nguyen: Asked if another meeting is going to be held. Does not feel comfortable voting on minutes that are conceptual, and the members have not been able to see how they have changed.

The meeting minutes were not approved. The agenda item was tabled. A meeting will be scheduled to approve the meeting minutes.

5. For Information: Presentation of Colorado's Enabling Legislation and Rules Development Process Related to that State's Natural Medicine Health Act

Lorey Bratten, Program Director, Natural Medicine Board, Colorado Department of Regulatory Agencies

- In 2022, Proposition 122 referred to as the Natural Medicine Health Act of 2002, was a citizeninitiated measure related to the use of certain plants or fungi for people 21 years of age or older.
- The Act received approval from Colorado voters in the November 2022 Colorado general election.
- The Act decriminalized cultivation, possession, and personal use of natural medicines for individuals over 21.
- Directed the Department of Regulatory Agencies (DORA) to establish regulated access programs for natural medicines.
- Established the Natural Medicine Advisory Board for the purpose of advising DORA on the implementation of the regulated access program.
- Proposition 122 permits individuals and local municipalities to regulate the time, place, and manner
 of the operation of healing centers.
- Seals the criminal records of individuals who have completed a sentence for a conviction that is no longer considered a crime pursuant to the legislation.
- Protects conduct permitted by the Natural Medicine Health Act.
- Several types of natural medicine are included such as Dimethyltryptamine (DMT), ibogaine, mescaline (excludes peyote), psilocybin or psilocin.
- Now and until June 1, 2026, natural medicine is specifically only psilocybin or psilocin.
- After June 1, 2026, if recommended by both the working group and the Advisory Board, the department can determine if other natural medicines will be included.
- Regulation for licensed facilitation services, cultivation, manufacturing, transportation, possession, distribution, and handling under the Act fell under DORA.
- In 2023, Senate Bill 23-290 was introduced to clean up the measures in the Act.
- Senate Bill 23-290 allowed the Natural Medicine Access Program to facilitate the licenses and manage the active facilitation, modified so the Department of Revenue (DOR) has oversight of manufacturing and cultivation, and extended the implementation deadlines to December 31, 2024.
- Additional duties added to DORA: establish the Federally Recognized Tribes and Indigenous Community Working Group and Advisory Board, and annual reporting in coordination with DOR.

- DOR is responsible for licensing and regulating healing centers, cultivations, manufacturers, and testing facilities under a new Natural Medicine Division.
- SB23-290 also had some personal use provisions; allows for personal cultivation, adults to share with other adults 21 years of age or older, no renumeration, no manufacturing with inherently dangerous substances, no open and public display or consumption is allowed, and established offenses for violations.
- From the Advisory Board's establishment, subcommittees were created.
- The subcommittees delivered 66 pages of recommendations for DOR and DORA.
- The Tribal Group consists of 7 members from Federally Recognized Tribes and 2 members who are indigenous but not a member of a Federally Recognized Tribe.
- The Tribal Group was set out to study avoiding misappropriation and exploitation, avoiding excessive commercialization, and any conservation issues.
- The Tribal Group is currently working on a report, and it will be provided to the Advisory Board in early 2025.
- Senate Bill 198 authorizes the director of the Division of Professions and Occupations to approve training programs.
- All rules and information are available online at https://dpo.colorado.gov/NaturalMedicine.

Ouestions:

Dr. Mujeeb Shad: Asked if they are making sure the clinics who are authorized are going to have experienced and trained psychotherapists.

Kate Cotter: Asked if there is a list of approved training programs.

Senator Rochelle Nguyen: Asked how long it took to get the training programs up, if they are local, and average costs for the training.

Dr. Dustin Hines: Asked what some of the key metrics they are looking for to come in and grow.

Diane Goldstein: Asked if there is anything they would have done differently.

Dr. Mujeeb Shad: Asked if there is a recommendation in the rules and regulations about what kind of dosages will be used.

- **6. For Information:** Presentation Discussing State and Federal Laws related to Psychedelic Medicines Kate Cotter, Executive Director of Nevada Coalition for Psychedelic Medicines
 - Several drug laws were consolidated under the Comprehensive Drug Abuse Prevention and Control Act of 1970.
 - Title II of the Act created the legal framework which regulates the manufacture, distribution, and use of controlled substances.
 - The Controlled Substance Act (CSA) is codified within Title 21 of the United States Code.
 - Two key components of the Controlled Substance Act are drug schedules and enforcement and regulation.
 - Key sections of the CSA are section 812- Schedules of Controlled Substances, section 823-Registration Requirements, section 841- Prohibited Acts A, section 846- Attempt and Conspiracy, section 871- Attorney General's Authority, and section 952- Import and Export of Controlled Substances.

- CSA outlines Schedules I-V, defined based on potential for abuse, medical use, and degree of dependence the substance may cause.
- Most psychedelics are Schedule I and section 812 outlines Schedule I examples relevant to psychedelics.
- Section 823 provides the requirements around research.
- Section 841 outlines the penalties for the illegal manufacture, distribution, and dispensing of controlled substances. Penalties are based on the Schedule and the amount involved.
- The Drug Enforcement Administration (DEA) works with the Food and Drug Administration to ensure the drug scheduling is based on scientific evidence along with enforcement considerations.
- The DEA is the primary enforcement agency and is responsible for scheduling, rescheduling, and enforcing. It also regulates manufacture, distribution, and dispensing of controlled substances.
- The FDA is responsible for scientific and medical evaluation of substances. They provide recommendations to the DEA based on medical use, safety, and abuse potential.
- To reschedule a substance, Congress can directly change the scheduling through legislation, or a petition can be submitted by DEA, Health and Human Services, or an external party.
- Nevada Revised Statutes (NRS) Chapter 453 is the primary legal framework for psychedelics.
- Nevada's system is like the Federal system.
- Religious use is codified in NRS 453.541 and is like Federal.
- Regarding research, Nevada is very stringent.
- The first category of drug policy reform is research.
- The second category, deprioritization is referred to as "lowest law enforcement priority."
- The third category, limits on enforcement funding, forbids law enforcement from using government funds to enforce certain laws.
- The fourth category, defelonization, reduces the penalties from a felony to a less serious crime such as a misdemeanor.
- The fifth category, decriminalization, reduces the penalties to an offense not considered a criminal offense.
- The sixth category, legalization of cultivation and sharing, allows adults to use, possess, cultivate, and share nonsynthetic compounds as long it is non-transactional.
- The seventh category, legalization of supervised consumption, relates to the Oregon and Colorado regulated access models for supervised administration of psychedelic substances.
- The eighth category, legalization of a regulated market, which would be akin to alcohol or cannabis where there may be age restrictions but essentially can walk in off the street and buy the substance.
- Currently, Nevada is at the first level with the research.

Questions/Comments:

- Dr. Mujeeb Shad: Asked if there are any regulations against ketamine.
- Diane Goldstein: Commented the federal government does not fund research that promotes the legalization or efficacy of any drug or other substance included in Schedule I. It is critically important for this working group to understand why they are in the cycle relative to the issues of research and efficacy. Part of the work of the working group is to address the gaps. Schedule I was political and not based on science.
- Dr. Dustin Hines: Commented the systems are complex and big, however is not defending the system Diane Goldstein talked about. The system is broken.
- Terry Kerns: Commented in looking at some of the systems put in place with cannabis legalization. One of the things missed was knowing some of the downstream effects, i.e., impaired driving. Proposed looking at downward effects and what impaired driving looks like in the state.

• Joshua Garber: Suggested adding weights of the laws, the breakdown of the different Schedules, weights, and the crime associated with them as well as the trafficking weight.

Marla McDade Williams asked members of the public if there were any comments regarding the presentation.

There were no comments.

- 7. For Possible Action: Approval of items to develop a strategic, measurable and actionable plan allowing access to safe and affordable entheogens so that such entheogens may be used for therapeutic purposes Marla McDade Williams, Chair
 - The legislation that enacted the working group has a provision that requires the working group to develop a strategic, measurable, and actionable plan allowing access to safe and affordable entheogens so that such entheogens may be used for therapeutic purposes. The plan is included in the draft report.
 - The working group can work through page 6 of the draft report or agenda item #8 can be considered in whole.

Comments:

- Senator Rochelle Nguyen: Commented some of the conversations in the meeting today are not included in the report. The report does not accurately reflect the work. The Cannabis Advisory Commission report can be provided as an example for the framework. Recommended designating a subcommittee to finalize the report and scheduling a meeting prior to the report being submitted.
- Assemblyman Max Carter: Commented is not comfortable with the draft report. It does not follow the intent. A deep dive into the contributing factors was supposed to take place and come up with an actionable plan. The actionable plan is not a plan at all. Ketamine is mentioned and it is not an entheogen.

The agenda item was tabled.

8. For Possible Action: Review and Possible Approval of the Draft Report Describing the Activities, Findings, Conclusions and Recommendations of the Working Group to the Director of the Legislative Counsel Bureau for Transmittal to the 83rd Session of the Legislature to be Submitted in Compliance with Senate Bill 242 from the 2023 Legislative Session Marla McDade Williams, Chair

The agenda item was tabled.

9. For Possible Action: Discussion of Future Topics and Work Plan for Working Group and Approval of Next Meeting Date

Marla McDade Williams, Chair

- A subcommittee will be established which will include Jonathan Dalton, Dr. Dustin Hines, Mark McBride, Assemblyman Max Carter, and Senator Rochelle Nguyen.
- A fourth meeting will be scheduled to adopt the report developed by the subcommittee.

Comments:

Jonathan Dalton: Recommended Kate Cotter be on the subcommittee.

Dr. Dustin Hines: Commented as a subject matter expert, has brought many references to the committee, and can bring all the facts. The facts need to be in the report. Recent references need to be populated in the document.

10. Public Comment

There was no public comment.

11. Adjournment

The meeting adjourned at 10:24 a.m.

