Natural Medicine Division

Listening Sessions

SB 23-290 Overview & Introduction

Dominique Mendiola, Senior Director, Department of Revenue Natural Medicine Division
Allison Robinette, Director of Policy & Regulatory Affairs, Department of Revenue Natural Medicine Division

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Agenda

September 5, 2023

I. Introduction to Natural Medicine Division (Division)

II. Presentation of SB 23-290

- ➢ Statutory Responsibilities Assigned to DOR

III. Overview of Priority Focus Areas presented to the Natural Medicine Advisory Board

IV. Anticipated Implementation Timeline

V. Q&A Opportunity - Priorities & Implementation

VI. Listening Session Overview & Schedule

- ➢ Topics
- ➢ September Schedule

VII. Q&A Opportunity - Listening Sessions

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Natural Medicine Division

Introduction

Heidi Humphreys, State Licensing Authority (Interim DOR Executive Director)

Dominique Mendiola, Senior Director

Kyle Lambert, Deputy Senior Director

Allison Robinette, Director of Policy & Regulatory Affairs

Cash Funded Program

Staffing - Leveraging Existing State Resources & Subject Matter Expertise

Coordination with Other State Agencies

Programming - Integrating New Licensing Functions into Existing Platforms

DOR-MED Areas of Expertise

- **Cultivation & Manufacturing Oversight:** Security requirements; permitted and prohibited chemicals; waste management; packaging & labeling; keeping pace w/innovation
- **Inventory Tracking:** Manifest requirements
- **Health & Safety Protocols:** Adverse Health Event Reporting
- **Data Driven Strategies:** Market data monitoring, risk-based intervention strategies
- **Licensing Application Development & Procedures:** Licensing processes for cultivation, manufacture, transport, and testing operations
- **Laboratory Testing Program Oversight**: Testing standards & Certification processes
- **Regulatory Oversight Involving Schedule I Controlled Substances**: Experience navigating challenges with federal law and opportunity to inform a federal framework
- **Social Equity Considerations**: Lessons learned / Impacts from the War on Drugs

Prop 122 to SB 23-290

Signed May 23, 2023

- **Natural Medicine Defined**
  - Psilocybin & Psilocyn (Initially)
  - Ibogaine (Prior to 2026)
  - DMT, Mescaline (2026)
- **Primary Code Changes**
  - Title 12
  - Title 25
  - Title 44
  - Titles 16 & 18
- **Outline of Provisions**
  - DORA Regulatory Program
  - DOR Regulatory Program
  - CDPHE Regulatory Role
  - Personal Use Provisions
- **Implementation Timeline Extended**
  - Extended Timeline for Rulemaking & Applications

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SB 23-290

Regulatory Program - DOR

The Department of Revenue (DOR) is responsible for licensing and regulating healing centers, cultivations, manufacturers, and testing facilities under a new Natural Medicine Division.

Other responsibilities include:

- Testing Program (coordination with CDPHE)
- Data collection (LE incidents, adverse health events, healthcare system impacts, consumer protection claims, behavioral health impacts)
- Public education campaigns
- Training materials for first and multi-responders
- Annual Reporting (in coordination with DORA)

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State Licensing Authority

Powers & Duties

- Application Intake: On or before December 31, 2024
- Licensing and Enforcement powers
- Reporting, Public Education, & Training duties
- Other Duties & Limitations:
  - Establish an equitable and inclusive program
  - Measures to prevent youth access
  - Production management
  - Measures to prevent exploitation & commercialization

State Licensing Authority

Rulemaking Authority

Mandatory Rulemaking: *The State Licensing Authority shall promulgate rules…*

- General licensing requirements; qualifications and eligibility requirements for licensure; permitted and prohibited financial interests; testing program; regulation of licensed premises; transportation requirements; production management; record keeping; etc.

Other Requirements & Limitations:

- SLA shall consult with the Natural Medicine Advisory Board when considering and promulgating rules

Priority Focus Areas

Presented to the Natural Medicine Advisory Board

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Priority Focus Areas

- Data Collection
- Develop and promote training materials for first responders and multi-responders
- Permissible / Prohibited Financial Interests in a License
- Regulation of Licensed Premises
- Product Requirements and Restrictions
- Develop and promote public education campaigns
- Natural Medicine Cultivation
- Manufacturing of Natural Medicine Products
- Storage and Transport
- Licensing Standards & Qualifications

Anticipated Implementation Timeline

Task / Milestone	*Goal Timing*
Data Collection & Reporting Requirements - Identify agencies required for coordination - Establish data collection process / policy - Establish annual reporting plan in coordination with DORA	July-December 2023
Initial Fact Finding Work Groups Focused On: - Public education campaign - First / multi responder training - Testing program standards	July-December 2023
Rulemaking Stakeholder Work Groups	January 2024 - June 2024
Natural Medicine Advisory Board Consultation - Present general rulemaking topics - Discuss proposed rules	*January / February / March 2024 NMAB meeting*

Anticipated Implementation Timeline

DOR GOAL EFFECTIVE DATE FOR RULES: 10/1/2024	
Task / Milestone	***Goal Timing***
Rulemaking File Permanent Rulemaking Hearing Notice	March 1, 2024
Rulemaking Notice Published in Colorado Register (procedural step)	March 25, 2024
Rulemaking Permanent Rulemaking Hearing	April 14, 2024
Rulemaking SLA adopts final rules	May 1, 2024
Rulemaking *Earliest possible effective date*	June 14, 2024* **Even with earlier effective date, may not being accepting applications before December 31, 2024*

Q & A Opportunity

Focus Areas & Implementation

Listening Sessions Schedule

September

- **September 12th:** *First & Multi-Responder Training Meeting #1*
  - 2:00 pm - 3:00 pm (MDT)
- **September 22nd:** *Public Education Campaign Meeting #1*
  - 2:00 pm - 3:00 pm (MDT)
- **September 27th:** *Testing Program Meeting #1*
  - 10:00 am - 11:00 am (MDT)
- **October 3rd:** *Cultivation & Manufacturing Practices Meeting #1*
  - 10:00 am - 11:00 am (MDT)

Q & A Opportunity

Listening Sessions