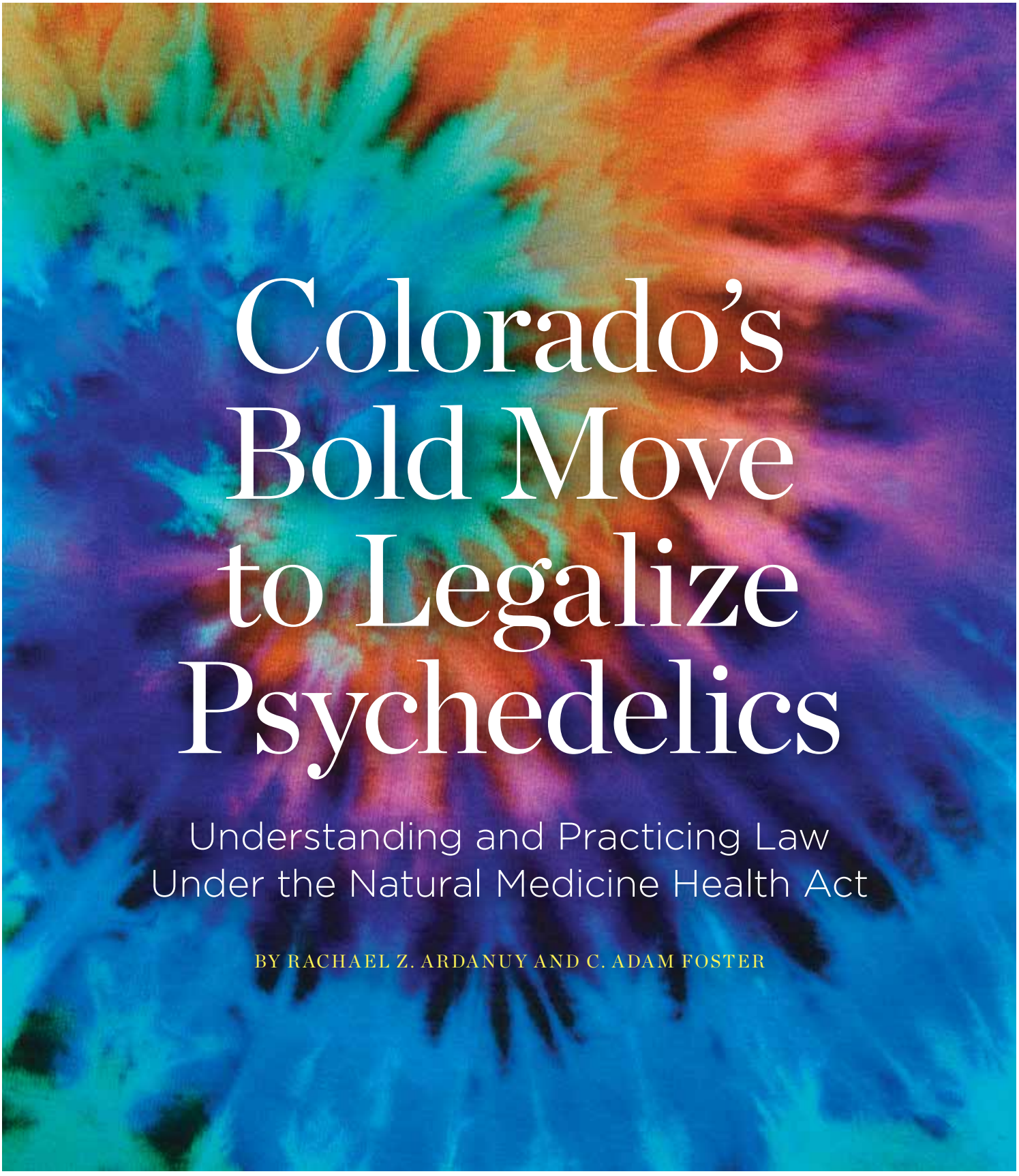

Colorado's Bold Move to Legalize Psychedelics

Understanding and Practicing Law Under the Natural Medicine Health Act

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This article summarizes key provisions of the Natural Medicine Health Act and explains how natural medicine services will be regulated in Colorado.

Psychedelics[1] are a class of drugs that trigger changes in perception and altered states of consciousness. In November 2020, Oregon voters passed ballot measure 109, the Oregon Psilocybin Services Act (Oregon PSA),[2] which was the first state law to create a state-legal, regulated market for psychedelic psilocybin products. Colorado voters followed suit in November 2022 by approving Proposition 122, the Colorado Natural Medicine Health Act of 2022 (NMHA). The NMHA contains two important prongs. First, it defines certain psychedelics, including psilocybin mushrooms, as decriminalized "natural medicine" that is legal to cultivate and possess in personal quantities but not to produce at commercial scale or to sell or exchange for any other type of valuable consideration. Second, the NMHA creates a relatively narrow and tightly regulated therapeutic path for adults to legally purchase psilocybin[3] products and consume them at a licensed healing center under the supervision of a licensed facilitator. As of the date of this article, Colorado and Oregon are the only two US states that have legalized psychedelics at the state level, but other states appear likely to pass similar provisions.[4]

Archeological evidence indicates that people have been using psilocybin mushrooms for spiritual purposes for thousands of years.[5] And most psychedelics have relatively few side effects and a comparatively low potential for abuse.[6] Yet most psychedelics are illegal to possess or use for medical or recreational purposes in the United States under the Controlled Substances Act (CSA), 21 USC §§ 801 et seq., and analogous state law provisions. Many well-known psychedelics, including psilocybin mushrooms, are classified as schedule I controlled substances under the CSA. This means that, as far as federal law is concerned, these drugs "have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse."[7] But like marijuana,[8] another scheduled drug under the CSA,[9] new research is demonstrating that many psychedelics likely have far greater medicinal value, and far lower risks to health and safety, than the current classification of these substances would indicate.[10]

"Archeological evidence indicates that people have been using psilocybin mushrooms for spiritual purposes for thousands of years. And most psychedelics have relatively few side effects and a comparatively low potential for abuse."

This article briefly describes key provisions of federal law governing psychedelics, provides a high-level overview of the NMHA, and highlights key areas of law affected by the NMHA. It also offers practical tips for Colorado attorneys and flags some key implementation and business planning considerations for natural medicine services.

Current US Federal Law and the Pharmaceutical Model

Existing US federal law permits research involving schedule I drugs under certain narrowly defined circumstances. The Food, Drug, and Cosmetics Act (FD&C Act), 21 USC §§ 301 et seq., gives the US Food and Drug Administration (FDA) the authority to oversee the safety and approval of new drugs in general. Additionally, researchers working with schedule I controlled substances must be licensed by the US Drug Enforcement Agency (DEA) and follow rigorous security protocols.[11] Thus, although it is possible to legally perform research on schedule I controlled substances under federal law, the process is expensive and time consuming.

For example, in 2018, COMPASS Pathways plc (Compass) received Breakthrough Therapy designation from the FDA[12] to research the use of a proprietary crystalline psilocybin formulation as a potential treatment for treatment resistant depression. Importantly, Compass acknowledges that for a product containing psilocybin or psilocyn to be legally marketed in the US, either those substances would have to be removed from schedule I and placed under a less restrictive schedule under the CSA, or its psilocybin-containing pharmaceutical drugs would have to be specifically scheduled by the DEA to fall somewhere under schedules II through IV.[13]

The FD&C Act contains no exemption for state laws that purport to legalize or decriminalize drugs that the FDA has not recognized as safe or otherwise approved for human use. Similarly, neither the NMHA nor the Oregon PSA comply with the CSA because both decriminalize under state law a schedule I controlled substance—psilocyn—and offer a legal path to access it under state law. This creates significant regulatory uncertainty because the federal government's tolerance of state-legal activities that violate federal law is dependent on the law enforcement priorities articulated by the current presidential administration and attorney general.

State laws legalizing marijuana provide a useful analogy. Although marijuana is currently a schedule I controlled substance under the CSA, 38 US states have now authorized its medical use, and 24 states have authorized its recreational use by adults aged 21 or older. Thus, there is precedent for the widespread legalization and use of a schedule I controlled substance under state law despite its continued illegality under federal law. That said, there are significant differences between psilocybin and marijuana in terms of the drug's effects and how people use it, the public's perception of it, and the number of states where the substance is legal. Although psilocybin may very well follow a similar path to widespread public acceptance and legalization at the state level, this is far from inevitable.

NMHA Overview

During the 2023 legislative session, the Colorado General Assembly enacted Senate Bill 290, which amended and clarified key provisions of the citizen-enacted NMHA. This section provides an overview of the NMHA, as amended by SB 290. The NMHA makes an important distinction between the personal use of natural medicine, which was broadly decriminalized in November 2022, and the regulated, therapeutic use of natural medicine, which is legalized under certain narrow circumstances.

Personal Use

The NMHA broadly decriminalizes the cultivation, possession, consumption, and sharing of natural medicine in quantities appropriate for "personal use" for adults aged 21 and older, so long as no money or other consideration is involved. Notably, the definition of "personal use" permits sharing within the context of counseling, spiritual guidance, beneficial community-based use and healing, supported use, or related services, and does not prohibit receiving remuneration only for such related services, provided that certain notice is provided and no advertising is made regarding the natural medicine offered.[14] In contrast, money—or any other valuable consideration—can only change hands in connection with the therapeutic use of natural medicine at a state-licensed healing center[15] under the supervision of a licensed facilitator.

NMHA: KEY DICHOTOMIES

The NMHA sets forth two key dichotomies: (1) between unregulated decriminalized natural medicine and licensed natural medicine products and services; and (2) allocation of regulatory authority between DORA and DOR in the context of state-licensed natural medicine products and services. Tables 1 and 2 expand on these points.

Legislative Declaration

The NMHA's legislative declaration opens by stating that Colorado voters "find and declare that":

> Colorado's current approach to mental health has failed to fulfill its promise. Coloradans deserve more tools to address mental health issues, including approaches such as natural medicines that are grounded in treatment, recovery, health, and wellness rather than criminalization, stigma, suffering, and punishment.[16]

The declaration expands on these concepts by finding that:

> An extensive and growing body of research is advancing to support the efficacy of natural medicines combined with psychotherapy as treatment for depression, anxiety, substance use disorders, end-of-life distress, and other conditions.[17]

Thus, Colorado voters concluded that Colorado should reduce its focus on punishing those who suffer from mental health disorders and instead permit the use of natural medicine with a focus on education and harm reduction. In SB 290, the General Assembly supplemented these findings by adding that care must be taken to protect the indigenous use of natural medicine and prevent the further exploitation or appropriation of indigenous practices by unscrupulous actors.[18] The General Assembly also found that natural medicine's "potential must be appropriately balanced with the health and safety risks that it could pose to consumers."[19]

Definitions

The definitions section[20] is a good jumping off point for describing the NMHA's overall regulatory structure. Importantly, SB 290 amended the NMHA by limiting the current definition of "natural medicine" in the context of licensed natural medicine services to psilocybin and psilocyn only. Dimethyltryptamine (DMT) and mescaline[21] are eligible to be added to the definition of legal natural medicine if recommended by the new state natural medicine advisory board (board) and approved by the director and the executive director of the state licensing authority for inclusion on or after June 1, 2026. There is no time limitation on when the board may add ibogaine to the definition of natural medicine.[22]

Note that psilocybin, ibogaine, DMT, and mescaline are all currently included under the definition of decriminalized natural medicine under CRS § 12-170-104(12). The definition of natural medicine excludes synthetic forms or synthetic analogs of these substances in both the NMHA's decriminalization provisions and its natural medicine services provisions.

Licensed Natural Medicine Services

Natural medicine services are defined as "a preparation session, administration session, and integration session" provided in compliance with the NMHA.[23] Thus, a "participant"[24] will

“Before the participant consumes natural medicine, the participant and facilitator must meet for a ‘preparation session.’ The preparation session will include a screening component to determine whether the participant is an appropriate candidate to consume natural medicine and, if so, to educate the participant on what to expect and what to do if they experience health problems or psychological distress during the administration session.”

engage in three distinct, statutorily defined sessions with a facilitator. Before the participant consumes natural medicine, the participant and facilitator must meet for a “preparation session.”[25] The preparation session will include a screening component to determine whether the participant is an appropriate candidate to consume natural medicine and, if so, to educate the participant on what to expect and what to do if they experience health problems or psychological distress during the administration session.[26] During the “administration session” the participant will consume the natural medicine under the facilitator’s supervision at a licensed healing center.[27] The last of the three sessions is the “integration session,” during which the facilitator and participant meet to discuss the participant’s experience.[28]

Natural medicine services can be provided at either a “healing center”[29] licensed by the state specifically for provision of natural medicine services, or a “health-care facility,” such as a hospital, doctor’s office, or long-term care facility that is licensed or otherwise permitted by law to offer medical treatment.[30] In other words, natural medicine services may be lawfully provided at either a healing center under the supervision of a licensed facilitator, or at a healthcare facility under the supervision of a medical doctor or other qualified health professional.[31]

Dual Regulatory Structure

Proposition 122 initially placed licensing of both facilitators and healing centers under the purview of the Colorado Department of Regulatory Agencies (DORA). Although DORA has deep experience managing professional licensing programs, it lacks institutional experience regulating the manufacture or sale of products. SB 290 addressed this issue by moving authority to regulate and tax healing centers and natural medicine products to the Colorado Department of Revenue (DOR) Natural Medicine Division.

CRS § 12-170-105 delegates various powers to the director of DORA’s division of professions and occupations (the division), including requirements for the safe provision of natural medicine services and natural medicine products. These administrative rules will cover a wide variety of topics including, at a minimum:

- “parameters for a preparation session, an administration session, and an integration session”;
- warnings or disclaimers and educational materials that must be provided to a participant prior to an administration session;
- requirements for participant consent forms;
- requirements for facilitator supervision of individual and group administration sessions;
- facilitator licensing requirements;
- natural medicine dosage limits;
- rules governing remuneration for natural medicine products and services;
- rules governing permitted ownership and financial interests in healing centers; and
- marketing and advertising standards and recordkeeping requirements.[32]

The division must begin accepting new license applications on or before December 31, 2024, and will initially prioritize applications submitted by Colorado residents.[33] The NMHA also mandates that, where financially feasible, administrative rules should minimize barriers to “persons from communities that have been disproportionately harmed by high rates of arrest for controlled substances, persons who face barriers to health-care access, persons who have traditional, tribal, or Indigenous history with natural medicine” and veterans who wish to become licensed as facilitators, operate a licensed healing center, or access natural medicine as a participant.[34]

The Board

The NMHA created a 15-member advisory board appointed by the governor to advise the division on implementation of the NMHA and rulemaking.[35] The statute also provides that certain members of the board must possess training and experience in various areas of medical, scientific, and cultural competency.[36] In addition to the topics for administrative rulemaking outlined above, the board is tasked

with advising the division and the state licensing authority on issues related to public health and public education regarding natural medicine. Additionally, the board will, on an ongoing basis, review pertinent studies and evidence to provide recommendations regarding whether natural medicine services "should be covered under health first Colorado or other insurance programs as a cost-effective intervention for various mental health conditions, including, but not limited to, end-of-life distress, substance use disorder, alcohol use disorder, depressive disorders, neurological disorders, cluster headaches, and posttraumatic stress disorder."[37]

Social Equity

The NMHA focuses on social equity and sustainability concerns in a way that is relatively new for a Colorado statute but may be a harbinger of concepts that will be included in future legislation covering a variety of subjects. In the context of the NMHA, the board is tasked with evaluating the sustainability of Colorado's natural medicine program and its impact on indigenous practitioners and cultures.[38] It is also required to make recommendations regarding removing barriers to licensure for low-income individuals and "[a]ffordable, equitable, ethical, and culturally responsible access to natural medicine" and to ensure that implementation and administration of the NMHA is "equitable and inclusive."[39]

Indigenous Rights

The NMHA is unique among Colorado business and occupational licensing statutes in terms of its focus on protecting and promoting the rights of both federally registered American Indian tribes and indigenous practitioners more generally.[40] CRS § 12-170-107 orders the division director to establish a working group to coordinate with tribes and indigenous people and study issues related to the commercialization of natural medicine, including avoiding the commercialization and misappropriation of indigenous culture and preventing overharvesting of the endangered peyote cactus, which some native people regard as a religious sacrament. The working group will also examine best practices for coordinating and fostering communication between those state agencies that regulate natural medicine and tribes and other indigenous stakeholders and communities.[41]

TABLE 1. DECRIMINALIZATION PRONG VERSUS LICENSING PRONG

DECRIMINALIZED PERSONAL USE	LICENSED USE
includes psilocybin/psilocyn, ibogaine, DMT, and mescaline (but not from a peyote cactus)	includes only psilocybin and psilocyn
Decriminalized natural medicine* may be produced, consumed, and gifted in personal use amounts, but no exchange of money or other valuable consideration is allowed.	Payment for licensed natural medicine* products and licensed facilitator services is permitted.
Unlicensed: Adults aged 21 and older have fairly broad rights to produce and use natural medicine in personal quantities as long as money does not change hands and there is no public consumption.	Licensed: Use and supply chain is strictly regulated by DORA and DOR.
exemption from criminal prosecution; essentially no economic or contract rights	statutory right to engage in licensed professions; enforceable business contracts
Unregulated: There is no government oversight of production or distribution. Laboratories can test personal use natural medicine, but no testing is required.	Tightly regulated: Licensed psilocybin products are tested** for contaminants and potency; the supply chain is closely monitored; products must be administered by licensed facilitators; and participants cannot take licensed products home.
CRS § 18-18-434	CRS §§ 12-170-101 et seq. (DORA); CRS §§ 44-50-101 et seq. (DOR)

* Natural medicine must be derived from a plant or fungus; chemical synthesis is not permitted.
** CDPHE coordinates with DOR to establish testing standards under CRS § 25-1.5-120.

Personal Use Protections

The legalized personal use of natural medicine will affect various areas of law, including criminal defense and law enforcement, real estate, family law, and municipal law. In the context of criminal defense and law enforcement, personal use of natural medicine under CRS § 18-18-434 cannot alone be the basis for detention, search, or arrest; cannot be the basis to support a probable cause determination of criminal activity;[42] and cannot be the basis for a child abuse or neglect finding (absent independent findings including all relevant factors).[43] Natural medicine is not subject to seizure and cannot be harmed or destroyed by law enforcement. While possession of natural medicine is generally legal in Colorado, some new criminal violations have been established, including the petty drug offenses for minors

under 21 possessing or consuming natural medicines,[44] open and public consumption,[45] violations related to personal cultivation of natural medicines,[46] and unlicensed manufacturing and sales.[47]

In the context of real estate, property owners are allowed to regulate and prohibit the cultivation or manufacture of natural medicine[48] but not the possession of natural medicine. In the context of family law, the courts shall not restrict or prohibit family time or determine that family time with a family member who is acting lawfully with respect to use or possession of natural medicine is not in the best interests of the child unless the court finds that the child's safety or mental, emotional, or physical health is at risk as a result of the family time.[49]

In contrast to the decriminalized personal use of natural medicine in the absence of any exchange of valuable consideration, natural medicine can only be provided in exchange for remuneration[50] in connection with statutorily defined "natural medicine services." Two state agencies are involved with the oversight of therapeutic use of natural medicine at licensed healing centers. DORA is responsible for regulating and licensing facilitators (individuals aged 21 or older who possess the requisite skill, training, and experience and have been licensed by the director of the division).[51] The DOR Natural Medicine Division is responsible for licensing and regulating healing centers and facilities that commercially produce, manufacture, and test natural medicine and natural medicine products that are administered by facilitators.[52]

TABLE 2. REGULATORY AUTHORITY OF DOR VERSUS DORA

DEPARTMENT OF REVENUE (DOR)	DEPARTMENT OF REGULATORY AGENCIES (DORA)
CRS §§ 44-50-101 et seq.	CRS §§ 12-170-101 et seq.
new Natural Medicine Division	new Office of Natural Medicine within the Division of Professions and Occupations
licenses healing centers and production facilities	oversees training program and professional (facilitator) licensing
oversight of natural medicine products (likely similar to "seed to sale" oversight and monitoring of licensed marijuana supply chain)	parallels with licensing for other health professionals; training exemptions for traditional and indigenous practitioners with requisite experience
regulates natural medicine product advertising	regulates facilitator/services advertising (including setting standards to avoid exploitation of indigenous cultures)

Limits on Local Regulation of Healing Centers

Municipalities may not ban or completely prohibit the establishment or operation of licensed healing centers or licensed healthcare facilities from providing natural medicine.[53] Nor may localities ban transportation of natural medicine through their boundaries on public roads by licensees, or adopt ordinances or regulations that are "unreasonable or in conflict with" the NMHA. This means that local governments are limited to reasonably regulating the time, place, and manner of operation of health centers. Thus, municipalities that intend to impose reasonable regulations on the location and operating hours for healing centers will need to enact pertinent local regulations, including updating zoning codes.

Importantly, the NMHA does not require local licensing of healing centers. This is an important contrast with Colorado's regulatory scheme for medical and retail marijuana, which requires operators to obtain a local marijuana business license and also grants municipalities the authority to enact an outright ban on marijuana businesses.[54] Many municipalities have begun exploring how they will manage healing centers, including whether they will require any permitting or licensing, while weighing the authority granted and limitations cast upon municipalities by the NMHA.

Time and Place Regulations

CRS § 12-170-112 mandates that "[a] local jurisdiction shall not prohibit" a state-licensed facilitator "from providing natural medicine services within its boundaries."[55] Additionally, CRS § 12-170-116 clarifies that, except where otherwise specified within the NMHA itself, the NMHA supersedes any conflicting provision of state or local law.

CRS § 44-50-104(5) sets out very similar limits on municipalities' authority to restrict the operation of healing centers and state-licensed businesses that cultivate, manufacture, test, store, or distribute natural medicine. Specifically, although the "local jurisdiction may enact ordinances or regulations governing the time, place and manner"[56] in which natural medicine businesses can operate, it "may not prohibit" operation of natural medicine businesses[57] or adopt local ordinances that are unreasonable or conflict with state law regarding licensing and operation of natural medicine businesses.[58]

Thus, it is not within municipalities' purview to enact any local law whose purpose or effect is to unreasonably restrict the operation of healing centers or access to natural medicine. As part of the 2024 rulemaking process, the DOR Natural Medicine Division is adopting extensive administrative regulations governing the licensing and operation of various types of natural medicine businesses that will have a significant practical impact on where and how natural medicine businesses can operate.

KEY BUSINESS PLANNING CONSIDERATIONS FOR NATURAL MEDICINE SERVICES

- **The size of the market for licensed services is unknown.** It is not clear how many adults will want to use a licensed psilocybin product at a licensed healing center under the supervision of a facilitator. This is particularly true since the personal cultivation and use of psilocybin mushrooms has been decriminalized in Colorado. But novice users or adults seeking a therapeutic experience will be willing to pay to use a tested, regulated product in a safe environment under the supervision of a licensed facilitator.

- **Pricing for licensed services is uncertain.** Pricing will depend on various factors, including how many facilitators and healing centers are licensed. The rulemaking process is ongoing as of the date of this article, and rules governing facilitator training, and production facility and healing center licensing will affect cost. It is also unclear whether other states will adopt similar statutes, which would presumably decrease the number of participants traveling to Colorado from out of state for natural medicine services.

- **Federal enforcement priorities could change.** As of the date of this article, the Biden administration has not indicated that it considers licensed natural medicine services to be a key law enforcement priority, but concerns regarding implementation or a different presidential administration could lead to enhanced scrutiny and enforcement from federal law enforcement authorities.

DORA is adopting similar regulations governing natural medicine facilitators.

The main practical questions that local governments must consider are where to allow various types of natural medicine businesses to operate and whether to restrict operating hours for natural medicine businesses or facilitators. Zoning provisions seeking to relegate natural medicine businesses or healing centers to areas where operations are impractical would likely violate the NMHA, as would restrictions on operating hours that make it impractical for facilitators to offer the full range of services that the NMHA and its implementing regulations authorize. In this regard it may be useful to look at ordinances governing analogous uses, such as operation of medical offices or counseling centers in the case of facilitators, or light manufacturing facilities in the case of businesses that manufacture, test, or distribute natural medicine products. Appellate holdings balancing time and place restrictions in the context of various types of protected speech may also offer some guidance.[59]

Facilitators or natural medicine business owners seeking to challenge the overall reasonableness of local ordinances restricting natural medicine activities may seek de novo district court review of the local ordinance by filing a declaratory judgment action. Specifically, Colorado Rule of Civil Procedure 57(b) permits a person "whose rights, status, or other legal relations are affected by a . . . municipal ordinance" to ask the district court to enter a declaratory judgment regarding the construction or validity of the local ordinance. CRCP 57 review will generally only be appropriate if the local ordinance conflicts with state law or unreasonably restricts natural medicine activities on its face.

In contrast, facilitators or business owners alleging that local officials have applied a facially valid local ordinance in an unreasonable manner will generally be obliged to seek district court review under CRCP 106(a)(4), which provides the normal means to challenge local officials' quasi-judicial acts. CRCP 106(a)(4) grants significant deference to local officials and requires a showing that the official or agency acted in an arbitrary or capricious matter for the district court to reverse their decision.

Conclusion

In recent years, Colorado has been an innovative laboratory of democracy in terms of drug policy. Colorado law now allows adults aged 21 and older to explore new cognitive vistas through the use and administration of psychedelics for healing, spiritual, and recreational purposes. The NMHA both decriminalized the personal use of natural medicine without remuneration and created an entirely new sphere of business activity where licensed facilitators can charge a fee to administer regulated natural medicine products to clients during facilitation sessions. Colorado indigenous natural medicine practitioners, lawyers, and entrepreneurs will continue to shape this movement and its enacting laws and regulations. CL


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NOTES

1. Many advocates prefer the term "entheogen" to refer to this class of substances. An entheogen is a substance—typically of plant origin—that is ingested to achieve an altered state of consciousness for religious or spiritual purposes.

2. The full text of the Act and updates regarding its implementation are available at https://www.oregon.gov/oha/ph/preventionwellness/pages/oregon-psilocybin-services.aspx.

3. The NMHA regulates both psilocybin and psilocyn. *See, e.g.*, CRS § 12-170-104(12)(a). After ingestion, the body converts psilocybin to psychoactive psilocyn. As used in this article, the term "psilocybin" includes psilocyn.

4. Clark, "Move Over Cannabis, the Movement to Legalize Psychedelic Mushrooms Is Ready to Share the Spotlight," *Natl. L. Rev.* (May 11, 2023), https://www.natlawreview.com/article/move-over-cannabis-movement-to-legalize-psychedelic-mushrooms-ready-to-share.

5. Samorini, "The Oldest Archeological Data Evidencing the Relationship of *Homo Sapiens* With Psychoactive Plants: A Worldwide Overview," 3 *J. of Psychedelic Stud.* 63 (June 1, 2019).

6. Nutt et al., "Drug Harms in the UK: A Multicriteria Decision Analysis," 376 *Lancet* 1558–65 (Nov. 6, 2010). Out of the 20 substances the authors analyzed, psychedelic mushrooms scored the lowest for individual and societal harm.

7. DEA Controlled Substance Schedules, https://www.deadiversion.usdoj.gov/schedules/schedules.html.

8. The correct scientific name for the plant is "cannabis," but Colorado state and US federal law use "marijuana" to refer to psychoactive cannabis. The 2018 Farm Bill legalized hemp, a non-psychoactive form of the cannabis plant with less than 0.3% THC on a dry weight basis.

9. On April 30, 2024, the Associated Press first reported that the DEA will propose to reclassify cannabis to schedule III from its current schedule I classification. Miller et al., "US Poised to Ease Restrictions on Marijuana in Historic Shift, but It'll Remain Controlled Substance," AP (Apr. 30, 2024), https://apnews.com/article/marijuana-biden-dea-criminal-justice-pot-f833a8dae6ceb31a8658a5d65832a3b8.

10. *See, e.g.*, Abbas et al. (Oregon Psilocybin Evidence Review Writing Group), *Oregon Psilocybin Advisory Board Rapid Evidence Review and Recommendations* (July 30, 2021) (compiling key medical and scientific studies and publications regarding psilocybin), https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Oregon%20Psilocybin%20Advisory%20Board%20Rapid%20Evidence%20Review.pdf.

11. The DEA's Diversion Control Division website sets out requirements for obtaining licenses to perform research on controlled substances and associated safety and security protocols. https://www.deadiversion.usdoj.gov/drugreg/registration.html.

12. According to the FDA, "Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)." https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy.

13. At page 21 of its September 21, 2020, prospectus filed with the US Securities Exchange Commission, Compass asserts: "Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while psilocybin and psilocyn are Schedule I controlled substances, products approved by the FDA for medical use in the United States that contain psilocybin or psilocyn should be placed in Schedules II-V, since approval by the FDA satisfies the 'accepted medical use' requirement." https://www.sec.gov/Archives/edgar/data/1816590/000162828020013779/compass424b4.htm#icfe282745ece49ac803f1aee527e8fa0_89.

14. CRS § 18-18-434(12)(d).

15. Final DORA regulations may also permit facilitators to administer natural medicine to certain participants at the participant's home, but as of the date of this article DORA has not promulgated final regulations for facilitators.

16. CRS § 12-170-102(1)(a).

17. CRS § 12-170-102(1)(c).

18. CRS § 12-170-102(2)(a)–(c).

19. CRS § 12-170-102(2)(d).

20. CRS § 12-170-104.

21. The definition of "mescaline" specifically excludes *Lophophora williamsii*—the peyote cactus—because peyote is used by some Native American practitioners as a religious sacrament and the proponents of the NMHA were worried about the overharvesting of naturally-occurring peyote.

22. Ibogaine is psychoactive indole alkaloid derived from a perennial shrub native to north Africa.

23. CRS § 12-170-104(14).

24. CRS § 12-170-104(15).

25. CRS § 12-170-104(16).

26. CRS § 12-170-105 sets out basic parameters for the preparation session, administration session, and integration session. As of the date of this article, DORA is finalizing administrative rules that will provide detailed guidance for facilitators and participants regarding the conduct of these sessions.

27. CRS § 12-170-104(1).

28. CRS § 12-170-104(10).

29. CRS § 12-170-104(8).

30. CRS § 12-170-104(9).

31. The board will adopt administrative regulations setting forth specific qualifications.

32. Current administrative rules and rulemaking updates can be found on DORA's natural medicine website, https://dpo.colorado.gov/NaturalMedicine, and also on the DOR Natural Medicine Division website, https://dnm.colorado.gov.

33. CRS § 12-170-105(1)(b).

34. CRS § 12-170-105(1)(d).

35. CRS § 12-170-106.

36. CRS § 12-170-106(2).

37. CRS § 12-170-106(6).

38. CRS § 12-170-106(7).

39. CRS § 12-170-106(5)(d).

40. CRS § 12-170-107. Under the NMHA, "'Federally recognized American tribe' has the same meaning as 'Indian Tribe' as defined by the federal 'Federally Recognized Indian Tribe List Act of 1994,' as amended." CRS § 12-170-104(7).

41. CRS § 12-170-107(1)(d).

42. CRS § 18-18-434(7)(a).

43. CRS § 19-3-103(4).

44. CRS § 18-18-434(1).

45. CRS § 18-18-434(2).

46. CRS § 18-18-434(3).

47. CRS § 18-18-434(4).

48. CRS § 18-18-434(10).

49. CRS § 19-3-103(4)(b).

50. CRS § 12-170-104(19) defines "remuneration" to effectively include any type of valuable consideration.

51. CRS § 12-170-104(6).

52. CRS § 44-50-201.

53. CRS § 44-50-104(5).

54. CRS § 44-10-301.

55. CRS § 44-50-104(5) further clarifies that the NMHA preempts conflicting local ordinances regarding the activities of natural medicine facilitators.

56. CRS § 44-50-104(5)(a).

57. CRS § 44-50-104(5)(b).

58. CRS § 44-50-104(5)(d).

59. *Cf. Reed v. Town of Gilbert*, 576 U.S. 155 (2015) (municipal sign regulations); Tisdale, "Regulating Sexually Oriented Businesses in Small Towns: Practical Tips and Preventive Medicine," 29 *Colo. Law.* 85 (Oct. 2000).