

## Policy Pitfalls and Challenges in Cannabis Regulation: Lessons from Colorado

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**Abstract** Since legalization of recreational marijuana use in 2012, Colorado has been a site of regulatory experimentation to support commercial sales. The path to legal recreational use began with a series of policy events that expanded the state’s medical marijuana program to include the creation of dispensaries and significantly increase the number of registered users. Voters convincingly passed a constitutional amendment that permitted commercial sale of recreational marijuana, and the state has created a regulatory model, based on a private business model, to address potential negative impacts. Colorado has used state- and local-level licensing, statutes, and regulations to address regulatory challenges regarding product potency, cannabis edibles, worksite and worker issues, impaired driving, commercial growing operations, locations of outlets and sites of use, and other policy issues. Jurisdictions considering recreational legalizations should consider a “harm reduction” approach to regulation that is responsive to addressing evolving adverse effects and addresses child safety, traffic safety, cannabis product safety, work and worksite safety, and other aspects of the business model in order to provide a careful approach to recreational use.

**Keywords** Cannabis · Marijuana regulation · Colorado

In 2012, Colorado became the second of two states in which the electorate voted to legalize recreational marijuana use. Commercial sale of cannabis products in Colorado started in January 2014, regulated by the Marijuana Enforcement Division of the state Department of Revenue, using a framework based on the Division’s Liquor Enforcement Division. Colorado had previously amended the constitution to permit medical marijuana use in 2000; and, through a series of legal and legislative events, the medical marijuana program became, for the most part, de facto legalization through registration. Hence, Colorado had some experience

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heading into legalization; however, overall, it has been a site of regulatory experimentation to support commercial sales and minimize adverse effects with variable success.

The purpose of this paper is to describe the historical context to Colorado’s legalization, discuss high-level regulatory models, and outline the regulatory framework used in Colorado. In addition, specific policy issues that may present potential challenges and pitfalls are listed and discussed as addressed in the state (Table 1). It is hoped that this information might be useful to other governmental entities considering marijuana legalization to mitigate possible negative civic, social, and health impacts. The potential therapeutic benefits and health harms are well-described elsewhere, perhaps most completely in the 2016 US National Academies of Sciences, Engineering and Medicine (NASEM) report, “The Health Effects of Cannabis and Cannabinoids, The Current State of Evidence and Recommendations for Research” (National Academies of Sciences, Engineering, and Medicine 2017).

## Colorado Historical Context

In 2000, Colorado voters approved the use of medical marijuana through an amendment to the state’s constitution using a framework similar to that passed in Oregon. The amendment called for a registry program to be run by a state health agency that the Governor decided would be the Colorado Department of Public Health and Environment (CDPHE). The program required a Colorado licensed physician document that an applicant for a “medical marijuana card” have one of seven conditions listed in the Institute of Medicine (now NASEM) report on Marijuana as Medicine (National Academies Institute of Medicine 2000). By 2004, there were only about 2000 people on the registry. In an attempt to address the nascent development of large medical marijuana outlets, CDPHE used policy to limit the number of patients per “primary care provider” (taken from the amendment language) to five patients. However, in 2007, a district judge invalidated this policy. A series of events, including the Obama administration’s directive to US Attorneys not to pursue medical marijuana cases and the Colorado State Board of Health’s failure to adopt a new proposed patient number limitation rule, created a setting for the emergence of a new small business model—the medical marijuana dispensary. Within a year, the number of registrants went to over 150,000—mainly males age 24–45 with the condition “chronic pain,” diagnosed often by less reputable physicians exploiting an easy source of substantial revenue. The local paper reported that the number of dispensaries in

**Table 1** Specific policy issues to consider in creating a regulatory framework for recreational marijuana

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Taxation framework
Potency of products
Edibles/food production
Worksite issues
Licensed healthcare workers
Impaired driving
Grow operations
Pesticide use
Permitted sites of recreational use
Transportation/delivery of products
Border/travel issues
Restrictions of locations and hours of sale for retail outlets
Money management (banking)
Advertising

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Denver exceeds the number of outlets of a popular national coffee chain. The medical marijuana program became, in the words of the State Attorney General, the de facto legalization of marijuana in Colorado.

The following year, the state legislature codified the dispensary model by passing a minimal regulatory framework. Overall public sentiment about marijuana use was positive; and, in 2012, the recreational marijuana constitutional amendment passed easily permitting commercial sale and allowing for local decision-making control (including the ability to ban sales). Since this time, the Department of Revenue has worked to create an evolving regulatory framework that accepts the private business model for commercial sales and is responsive to attempting to address negative impacts learned from experience.

## High-level Policy Considerations

Many US states (29 at the time of this article) have implemented medical marijuana programs. There are policy issues specific to medical cannabis that can inform decisions about recreational legalization and regulation. One is the issue of safety and efficacy as well as the ability for healthcare providers to balance therapeutic benefit and harms. There are challenges based on the US pharmaceutical regulatory model including dosing and uniformity of formulation and route of administration as well as the classification of marijuana by the federal government as a Schedule I controlled substance—one with “no currently accepted medical use, a high potential for abuse and no accepted safe use.” Also, there are concerns with approved conditions for research and state-to-state variation of regulations. Finally, there are issues of how the healthcare system addresses marijuana use—how practice is regulated through usual licensing of providers and facilities, how payers and insurers address use, laws that conflict with medical use such as in housing not owned by the patient, and the inability or unwillingness to use within the Department of Veterans Affairs healthcare system due to the Schedule I DEA classification.

Turning to legalization of recreational use, there are a number of major questions and potential approaches to consider. It is important to note the difference between decriminalization and legalization; eight US states and the District of Columbia have legalized recreational use and 14 other states have de-criminalized it. Decriminalization only addresses the criminal justice consequences of recreational use of cannabis such as arrest and incarceration for possession, while sale and possession remain illegal. Legalization allows for the regulation of growing, possession, use, and commercial sale.

In considering legalization, a government entity should be clear about the purpose of this policy as this can drive the regulatory model. The potential reasons for legalization include valuing libertarianism policy that prioritizes choice in individual behaviors (a belief that preventing such choices is not the government’s role). There is an argument that a substance with cannabis’ effect and impact should be regulated the same as other legally available substances such as tobacco and alcohol. There are policy makers who feel that the regulation permitted with legalization makes growing, distribution, and use safer. There are changing social norms developing with the new generation of political leaders and policy makers who currently use marijuana or used it in the past and have differing views on its harms and acceptability. Legalization clearly leads to new business and economic development, leading to new tax revenues for government purposes. And, it is important to recognize the effective influence of well-organized advocacy and public sentiment.

There are at least three types of high-level regulatory models: personal grow, private business, and government monopoly. There are also models that mix aspects of the different approaches. The personal grow model does not allow commercial sale but allows individuals to “grow their own.” Regulations can address the number of plants an individual may possess and can prohibit further distribution. A significant portion of Colorado’s medical marijuana program was based on this model. However, enforcement is difficult and this model suffers from issues such as where does one legally get the seeds or seedlings? Also, there could be issues regarding the ability to grow marijuana.

The private business model is the one currently used in Colorado and used or anticipated by other states implementing legalization. This is a market-driven model that includes business-based grow operations, cannabis product production, and retail sales. This approach affords great flexibility in detailed regulation but can be associated with significant monitoring and enforcement challenges. Most states use this model for alcohol sales.

There are some US states and Canadian provinces that use a “government monopoly” model for alcohol sales. In most cases, retail sales for hard liquor products produced by private businesses are through state or government outlets only. This model could be extended to grow operations that could provide additional regulatory protections or there could be a government monopoly in production and a private model for sales. Several Canadian provinces are planning on using a government monopoly model when legal recreational marijuana is implemented in 2018.

## Regulatory Framework in Colorado

In Colorado, both medical and recreational marijuana are regulated by the Marijuana Enforcement Division of the state Department of Revenue (DOR) although CDPHE still runs the medical marijuana registry per the state constitution. Along with licensing specific facilities and activities, the DOR has responsibilities for some state-level regulations, while local venues including counties and municipalities have other regulatory authority. Table 2 lists the different regulation areas for state and local jurisdictions. There are additional regulatory elements that

**Table 2** Colorado recreational marijuana regulations

### State-level regulations

- Licensing for retail stores, product manufactures, cultivation centers, testing facilities, transporters, and business operators
- State taxes
- State residency requirements for officers, managers, and employees
- Criminal background check requirements for all involved persons
- Producers and sellers cannot mix substances (tobacco, alcohol)
- Employers do not have to accommodate marijuana use or possession at the workplace
- Employers can enforce policies regarding marijuana use by employees
- Property owners can prohibit or regulate all on-site marijuana activity
- Driving under the influence of marijuana is a crime
- Edibles regulation (product type/appearance, packaging, potency)

### Local (county, municipality)-level regulations

- Time, place, manner, and number of marijuana establishment operations
- Procedures for the issuance, suspension, and revocation of a local license
- Schedule for annual operating, licensing, and application fees for marijuana establishments
- Civil penalties for violation of an ordinance or regulation governing the time, place, and manner of operation of a local marijuana establishment
- Local bans: allowed through ordinance or ballot measure

are included and could be added; however, the list above provides some guidance for jurisdictions contemplating legalization.

## Specific Policy Pitfalls

### Differential Taxation for Medical and Recreational Cannabis

Colorado has two constitutional amendments regarding cannabis—one for medical marijuana and one for recreational marijuana. The medical marijuana program is still very active driven, in part, by more socially acceptable reasons for use but perhaps by a deliberate differential tax rate (state taxes are 2.9% for medical marijuana and 15% for recreational marijuana sales). The differential rate while well-intended to support medical use continues to create potential abuse of the program by physicians and users. If a jurisdiction chooses to maintain a separate medical marijuana program, regulatory approaches should either decrease economic drivers of abuse or have tighter control of the medical program.

### Potency

Colorado's experience has demonstrated that through careful horticulture techniques, potency, measured by delta-9-tetrahydrocannabinol (THC) in cannabis plants, is significantly higher now than in the past. There are some that hypothesize this change was driven by the limitation in the number of plants possessed under medical marijuana programs; that is, six plants will provide more active drug if grown to have higher THC content. In addition, there are processes for concentrating THC in ingestible forms (e.g., oils, "shatter," and "wax") that have very high THC levels. Colorado's experience is that these higher concentrations translate to increases in THC overdoses, most notably in children, but also in THC-naïve adults. In 2017, Colorado attempted to address this by limiting the amount of THC in packaging—no more than 100 mg per individual package and 10 mg per "standard serving." Also, there are limits on how much product can be purchased by an individual per day (i.e., 28 g with conversions for concentrates and edibles), as well as how much can be in a person's possession (i.e., 28 g of concentrates or THC or up to six plants, only three of which are flowering).

### Edibles/Food

Marijuana in different forms has been ingested for millennia; however, in the USA, edible marijuana creates a regulatory conundrum. The U.S. Food and Drug Administration (FDA) has regulations that state that "food" is "adulterated" if it contains a "nonnutritive substance" and cannot be sold leading to banning such products by state regulators. As stated above, marijuana is a Schedule I drug and thus is classified as a nonnutritive, adulterating substance. In the medical marijuana program, CDPHE was directed to find a solution to allow for ingestible products and its administration; therefore, the term "edibles" was created for use in place of "food." This legal fiction has been adopted widely in cannabis programs across the nation and internationally and is associated with safety concerns requiring additional regulations primarily to protect children. Colorado requires child-resistant packaging and, in 2017, banned the production and sale of edibles shaped like animals, people, or fruit. However, there are still many different cannabis products that look like candy or other confections.

Another regulatory issue is that of food safety. Colorado does not have a regulatory framework to permit or require inspection of facilities that produce cannabis edibles for retail sale. The expertise to do this is in CDPHE but the Department has no authority for sanitary inspections. The DOR can require a sanitary inspection but this would be in response to a particular concern, not prophylactically. As in other food production settings, CDPHE has authority to investigate facilities in response to a foodborne infectious disease outbreak but this is a reactive strategy only. Regulations that are inclusive of ingestible marijuana products are an important consideration for legalization.

### **Worksite Issues**

Colorado law supports the ongoing use of drug-free workplace rules, which apply whether use is medicinal or recreational. There are ongoing concerns about how cannabis use impacts job performance particularly among drivers, soldiers, security guards, and others.

Healthcare workers present additional challenges for licensing boards. Policies are similar to those for excessive use or abuse of alcohol and working while impaired—leading to immediate suspension of the healthcare worker's license. Because marijuana stays in the system for days, it is difficult to determine the time of ingestion and the degree to which marijuana is affecting performance. This results in the healthcare worker being at risk of being found working while impaired for any marijuana use regardless of when it was last used.

### **Impaired Driving**

There are similar regulatory challenges for driving as well as working while impaired. There is no widely accepted, well-validated standard of use measurement linked by research to impairment. It is clear that ongoing use is associated with tolerance so the same level of THC will have different effects on performance for different individuals.

Despite objections raised by advocates, Colorado implemented a 5 nanograms THC in whole blood standard for driving under the influence—this applies to both recreational and medicinal use. Also, police can use their own judgment in determining impairment using standardized roadside sobriety testing and/or suspected use regardless of blood level of THC. Despite ongoing controversy about testing and standards, it is essential that jurisdictions pursuing legalization consider setting standards to support traffic safety.

### **Grow Operations**

In Colorado, cities or counties have the authority to issue, or deny, licenses for commercial grow operations under state regulations. Such operations are an area of legalization that has plagued Colorado with illegal grows, black-market sales, and illegal distribution in state and out of state along with associated crimes. There were 16 separate law enforcement actions for illegal growing in 2017 and these are only those in response to what has been discovered.

In 2017, the state legislature took steps to address the abuse of home-growing by outlawing “growing co-ops,” where individuals would pool resources to create large grow operations and thus avoid applicable licensing requirements and taxes. Also, the statute limits the number of plants per residence to 12 total regardless of the number of eligible adults in the residence. Government-run grow operations, as are being implemented by some Canadian provinces, should provide significant protection from illegal activity in this arena.

## **Pesticide Use**

Pesticide use for commercial grow operations is a regulatory issue. No pesticide is federally registered for use on cannabis and evidence on safety is lacking. Colorado (<https://www.colorado.gov/pacific/agplants/pesticide-use-cannabis-production-information>) and California (<http://www.cdpr.ca.gov/docs/cannabis/index.htm>) have lists of acceptable and unacceptable pesticides for marijuana cultivation; however, cannabis product production has been associated with pesticide levels above the acceptable health standards (up to 1200 times or greater) and the use of banned produces is still commonplace leading to product seizures. Required testing for pesticides should be a key consideration for policy makers.

## **Sites of Use**

A significant issue in Colorado relates to where the use of cannabis products is legal. Open and public use is prohibited under the constitutional amendment. This relegates use primarily to private residences although Denver is now offering “social marijuana use” licenses for agencies such as coffee shops and restaurants to provide a setting for use described as “cannabis clubs.” Hotels and multi-unit housing buildings can, and do, prohibit onsite use. Anticipating and addressing this significant policy challenge is likely to be critical as other jurisdictions consider recreational use legalization.

## **Border/Travel Issues**

Municipal, county, state, and national differences in cannabis regulation create many challenges on different geopolitical levels. Differential regulation can involve legality, commercial sales bans, purchase amounts, taxes, outlet locations/hours of operation, distribution approaches, and sites of use. Two bordering states have sued Colorado to recoup law enforcement costs for patrolling roads that cross state lines. Also, additional resources are required for adequate surveillance at airports and the prevention of illegal export. Policy issues are clear; but, enforcement and ongoing illegal trafficking remain important issues to consider.

## **Other Policy Issues**

There are a number of additional regulatory issues to consider for legalization implementation. Colorado has experienced issues with many of them. For example, outlet location restrictions are important to community members especially in residential neighborhoods and near schools. Colorado law allows for local control of locations that can lead to differential regulation as mentioned above. Hours of sale have a state limit (i.e., 8 am to midnight); but again, local control can create different restrictions such as shorter hours of operation. In terms of alcohol use, evidence demonstrates that outlet density (Campbell et al. 2009) and days of sale (Middleton et al. 2010) significantly affect excess use and associated adverse outcomes. These approaches to use control have not yet been tested in terms of cannabis use but provide guidance that might help shape policy.

Money management for commercial sales is another regulatory conundrum in the USA. Due to federal law where marijuana sales are illegal, banks cannot do business with cannabis operations. This impacts loans, deposits, and payments resulting in the development of large amounts of un-bankable cash that inevitably attracts criminal activity. There have been

associated impacts on the Denver housing market. For example, cannabis business owners who buy houses to create assets that can result in legally bankable income leads to a decrease of housing availability and higher home prices.

Advertising is another concern. In Colorado, separate regulations have been implemented for different media sources (e.g., print, broadcast, internet, billboards) in order to limit marketing to people under age 21 years. Colorado allows home delivery of cannabis products and transportation is regulated through courier licensing. Other transportation issues such as outlet delivery from large grow operations is a related regulatory issue to be considered.

## Conclusions and Recommendations

There are many regulatory issues associated with the safe, careful implementation of laws that legalize recreational marijuana use. Jurisdictions considering this direction should learn from the “early adopters” such as Colorado where new regulations were created in response to many unanticipated challenges. A key recommendation for consideration is to use a “harm reduction” framework with policies intended to minimize social, civic, and health harms that will inevitably be associated with recreation use legalization. Special policy considerations should include protection of newborns (i.e., during pregnancy), children, and adolescents where choice is not “informed” and harms are clear.

Key areas for policy makers to consider include child safety as mentioned above, issues around edibles and food/product safety, traffic safety, worker and worksites, impact of the business model including outlet availability and cultivation, and geopolitical border issues. There are tradeoffs between standardizing regulation through national policy versus allowing local regulatory autonomy; differential regulation can have many consequences. And, it is inevitable that there will be unanticipated outcomes that will arise necessitating a nimble and responsive regulatory framework able to address and limit adverse effects.

**Compliance with Ethical Standards** The article is in compliance with the protection of all human and animal rights.

**Conflict of Interest** The author declares that there is no conflict of interest.

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