BEFORE THE DEPARTMENT OF PUBLIC HEALTH
AND HUMAN SERVICES
OF THE STATE OF MONTANA

In the matter of the adoption of New Rule I and amendment of ARM 37.107.105, 37.107.117, 37.107.118, 37.107.120, 37.107.128, and 37.107.206 pertaining to Montana medical marijuana program	))))))	NOTICE OF ADOPTION AND AMENDMENT

TO: All Concerned Persons

1. On January 31, 2020, the Department of Public Health and Human Services published MAR Notice No. 37-907 pertaining to the public hearing on the proposed adoption and amendment of the above-stated rules at page 170 of the 2020 Montana Administrative Register, Issue Number 2.

2. The department has amended the following rules as proposed: ARM 37.107.105, 37.107.120, and 37.107.206.

3. The department has adopted the following rule as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE I [37.107.134] ADVERTISING (1) remains as proposed.
(2) A licensee may use the phrase "DPHHS Montana Medical Marijuana Program Licensed Provider" in its signage, on a website homepage, or on its promotional materials.

AUTH: 50-46-341, 50-46-344, MCA
IMP: 50-46-341, MCA

4. The department has amended the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

37.107.117 FEES (1) through (3) remain as proposed.
(4) A testing laboratory applicant must submit to the department with the initial application and renewal application an application fee of $2,000.
(4) and (5) remain as proposed but are renumbered (5) and (6).

AUTH: 50-46-344, MCA
IMP: 50-46-344, MCA

37.107.118 MARIJUANA AND MARIJUANA-INFUSED PRODUCTS PROVIDER LICENSEE REQUIREMENTS (1) through (18) remain as proposed.

(19) A licensee may not cultivate hemp or engage in hemp manufacturing at a registered premises.

(a) A licensee's marijuana or marijuana product that contains low levels of THC remains marijuana that must be tracked in the state's seed-to-sale program.

(20) remains as proposed.

(21) A licensee may only sell hemp cannabidiol (CBD) products sourced from hemp produced and sold ~~through the Montana Department of Agriculture Hemp Program~~ by a producer who is licensed by a state or tribe with a USDA-approved hemp production plan.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-308, 50-46-312, 50-46-319, 50-46-326, 50-46-328, 50-46-329, 50-46-330, MCA

37.107.128 LEGAL PROTECTIONS -- ALLOWABLE AMOUNTS (1) and (2) remain as proposed.

(3) Usable marijuana may be in the form of flower, marijuana-infused products, or concentrates. The following conversion shall be used to determine the allowable amounts of non-flower marijuana:

(a) 1 ounce of marijuana flower is equal to:

(i) 800 mg of THC in marijuana-infused products including edibles, or

(ii) 8 grams or 8 mL of THC in marijuana concentrate.

(b) remains as proposed.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-312, 50-46-319, 50-46-328, 50-46-329, 50-46-344, MCA

5. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: Many commenters asserted that the advertising ban unconstitutionally restricts the right to free speech guaranteed by the First Amendment, free speech is under attack, and "reasonable person" is not enforceable. Commenters also stated that because the MMP is a state-sanctioned legal program, businesses and individuals that are a part of the program are entitled to the same rights as any other legally established industry.

RESPONSE #1: The department disagrees with the conclusion that it is unconstitutional to restrict medical marijuana advertising. Prohibitions on advertising do not violate the constitutional right to free speech. The department must promulgate rules to implement statutes. "Statutory language must be construed according to its plain meaning and if the language is clear and unambiguous, no further interpretation is required." The Montana Supreme Court previously analyzed the advertising ban of 50-46-341, MCA, and concluded that it only prohibited commercial speech. Commercial speech is "accorded less constitutional protection than noncommercial speech." Mont. Cannabis Indus. Ass'n v. State, 2016 MT 44,

paragraph 64. The court reiterated that "marijuana use or possession unequivocally is an unlawful activity, so the ban on advertising does not involve lawful activity." Therefore, the court held that a statutory advertising ban does not rise to the level of a First Amendment violation.

COMMENT #2: Multiple comments were submitted stating that the advertising rule prevents awareness of medical marijuana businesses. Several comments stated that this is unfair because other businesses and pharmacies are allowed to advertise.

RESPONSE #2: Section 50-46-341(1), MCA expressly forbids the advertisement of marijuana or marijuana-related products. This rule is consistent with that prohibition and only further clarifies what constitutes the advertisement of marijuana or marijuana-related products.

This rule does not prohibit the advertisement of a business. Providers are able to advertise their business in any medium they choose. Many providers have already successfully advertised their businesses in newspapers, billboards, radio, and internet advertising campaigns without advertising marijuana.

The Montana Medical Marijuana Program (MMP) has a very limited purpose and scope: to provide medicine to people with debilitating conditions. The Montana Supreme Court used the Black's Law Dictionary definition of "advertising" in its Mont. Cannabis Indus. Ass'n v. State analysis. "Advertising is '[t]he action of drawing the public's attention to something to promote its sale." paragraph 63.

COMMENT #3: Commenters stated that the advertising ban is bad for patients. Several comments asserted that advertising is necessary, especially in light of untethering. Multiple commenters stated that cardholders need access to information in order to make educated decisions about which provider(s) to use.

RESPONSE #3: The MMP has a central office with staff readily available to all interested people. The MMP's website includes a list of licensed providers along with their general location and telephone number. Once a cardholder has a provider's name and phone number, they have the ability to reach out to multiple providers.

Providers may post non-prohibited content on a publicly accessible website and can utilize password protection to keep marijuana-specific information shielded from the general public. Interested cardholders can obtain passwords from the providers they contact to look at a provider's website. Or, the provider can provide a cardholder with the provider's dispensary address so a cardholder can visit it and discuss options with the provider in person.

COMMENT #4: One commenter asked why the state can use billboards with giant marijuana leaves, but providers cannot get information about medical marijuana or the MMP to the general public.

RESPONSE #4: The Montana Department of Transportation and the National Highway Traffic Safety Administration oversee those signs and are not subject to the Montana Medical Marijuana Act (Title 50, chapter 46, part 3, MCA). Again, this is a statutory prohibition and not set forth by rule.

COMMENT #5: A commenter stated that it would be better for an exception to the advertising prohibition that allows medical marijuana providers to identify that they are licensed by the MMP.

RESPONSE #5: The department agrees with this comment. Based upon feedback regarding the proposed rule's absolute prohibition on the use of the term "marijuana," the department amends the proposed rule. A licensee may use the phrase "DPHHS Montana Medical Marijuana Program Licensed Provider" in its signage, on a website homepage, or on its promotional materials.

COMMENT #6: Multiple commenters stated that the advertising rule is unfair because pharmaceutical and alcohol companies are allowed to advertise.

RESPONSE #6: Marijuana remains federally illegal. Pharmaceuticals and alcohol are not absolutely illegal under federal law. Those substances are heavily regulated by the federal government.

COMMENT #7: One commenter stated that the standard of a "reasonable person" is too vague and that it will be difficult to enforce these laws given the expansive amount of discretion from inspectors to determine what a "reasonable person" would assume is advertising.

RESPONSE #7: The department disagrees with this comment. The concept of a "reasonable person" is a widely used legal concept in both criminal and civil matters. The reasonable person is a hypothetical person standard who is of average awareness and understanding, though sufficiently thoughtful and reasonable. The primary function of the reasonable person is to attempt to assess the actual conduct of a party who is accused of negligence, or a breach of duty or foresight, by comparing what the person did in fact to what a different person, who would not be negligent or knowingly in breach of a duty, would have done. Read more at: Bouvier Law Dictionary - Reasonable Person (Reasonable Man or Reasonable Woman).

The MMP necessarily has discretion in its regulation of providers. Under Harlow v. Fitzgerald (1982), 457 U.S. 800, 102 S. Ct. 2727, 73 L. Ed. 2d 396, HN2 government officials performing discretionary functions are shielded from liability for civil damages only where their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have knowledge. Sacco v. High Country Indep. Press, 271 Mont. 209, citing Harlow, 457 U.S. at 818. It is impossible to regulate with black-and-white guidelines because program participants present an endless combination of situations. Providers are able to question the MMP's regulatory conclusions through the administrative hearing process.

COMMENT #8: One commenter noted that the fiscal note is not accurate. It does not mention the loss of income to the university system from out-of-state students paying 17,000.00 less in tuition each. That figure is from the MSU-Bozeman tuition averages for a full-time student. That is an impact of 1.7 million per 100 who change from out-of-state resident to in-state. This commenter suggests that the department needs to choose a figure that will be about one-third of total students with card as an estimate; otherwise, the statement is fiction.

RESPONSE #8: The department disagrees with this comment. The proposed rule implements the statute, which requires Montana residency. Individuals who do not meet the combined residency requirements of 50-46-302, MCA and 1-1-215, MCA, do not qualify to participate in the Montana Medical Marijuana Program.

COMMENT #9: A provider commented that many people move into Montana with pre-existing conditions and do not have the time to wait for their Montana state identification to arrive or have a long wait time for a DMV appointment. The commenter also stated that those people are not denied their prescriptions from drug stores, why should they be denied their other medications.

RESPONSE #9: The department appreciates the provider's concern but disagrees with the conclusion. This rule accurately implements the statutes requiring Montana residency. Written certifications issued to Montana cardholders are not transferable prescriptions. Individuals who do not meet the requirements for Montana residency are not eligible to participate in the Montana Medical Marijuana Program.

COMMENT #10: The state laboratory submitted a comment to address the proposed revision to ARM 37.107.117, which removes reference to the application fee for medical marijuana testing laboratories. It appears the fee language was inadvertently removed. The state laboratory requested the fee language remain as part of the rule. The department is authorized to charge fees for testing laboratories under 50-46-344(1)(l), MCA, and the fee is necessary to help offset the costs associated with licensing and inspecting medical marijuana testing laboratories. The department's state laboratory is responsible for the licensing and inspection of medical marijuana testing laboratories.

RESPONSE #10: The department agrees with this comment. The testing laboratory licensing fee was inadvertently deleted from this rule. It has been restored in the amended proposed rules.

COMMENT #11: A commenter stated that the proposed method for measuring canopy remains too vague. Mature flowering plants may extend the diameter of growth circumference based on strain, etc.

RESPONSE #11: The department disagrees with this comment. The department's method of measurement will include all plants, regardless of strain or size, within the

dedicated growing space. It is the provider's responsibility to comply with the provider's assigned canopy tier license.

COMMENT #12: A provider submitted a comment that the provider did not understand how to distinguish low-THC, high-CBD marijuana from hemp.

RESPONSE #12: A provider may produce low-THC, high-CBD marijuana in accordance with MMP regulations. Any cannabis cultivated, manufactured, and sold by a medical marijuana provider is considered marijuana and is considered marijuana under the provider's license. The provider must track the marijuana in the state's seed-to-sale tracking system. Beginning January 1, 2021, any product marketed as hemp-CBD must be sourced from a producer who is licensed by a state or tribe with a USDA-approved hemp production plan.

COMMENT #13: A provider commented that the department inaccurately measured their square feet of cultivation space and placed them in the wrong canopy tier. This provider stated that the department's method of determining a provider's canopy tier is too open to interpretation and was being inconsistently implemented by inspectors.

RESPONSE #13: The department disagrees with this comment. The department contacted all licensed providers in advance of the January 1, 2020, statutory effective date of the new canopy tier licensing system. The department's letter was sent via U.S. mail to the physical mailing addresses licensed providers registered with the department. That letter notified all licensed providers of their tentatively assigned canopy tier and set a 30-day deadline. That letter instructed providers to contact the department within 30 days if a provider disagreed with the tentative canopy tier designation. The department received and responded to multiple providers who contacted the department in that timeframe regarding the provider's assigned canopy tier level. As with any business, licensees are responsible for carefully reading their mail and following up with the department as necessary.

COMMENT #14: A commenter stated that CBD is legal and widely available at gas stations and many other stores. It is unfair and illegal for the MMP to prohibit providers from selling cannabidiol (CBD). Licensed Montana medical marijuana providers should not be restricted on the sale of these unregulated products, unless the over the counter (OTC) sales are also regulated.

RESPONSE #14: The department recognizes that CBD is widely sold at businesses around the state, but disagrees that it is sold legally or in compliance with the U.S. Food and Drug Administration (FDA) regulations. The FDA has approved only one CBD product, a prescription drug product to treat two rare, severe forms of epilepsy. CBD is widely available only because limited government resources have not yet caught up with regulation of products sold to the public. The FDA has issued multiple warnings to many CBD providers to immediately cease sales of many CBD items. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

COMMENT #15: Commenters stated that it is unconstitutional to place restrictions on providers' sale of CBD under the Commerce Clause in Art. I, Sec. 8, United States Constitution. Only Congress can regulate interstate commerce, and laws requiring only in-state sources of products that are otherwise available in interstate commerce usurp congressional authority. Wyoming v. Oklahoma, 502 U.S. 437, 112 S. Ct. 789 (1992).

RESPONSE #15: The department disagrees with this comment. The widespread availability of CBD does not mean that CBD is legally available. The department must ensure that the program's participants, many of whom are medically fragile, do not blindly purchase products that are subject to, but not yet approved by, the FDA. The FDA has classified CBD as a drug but has not finalized its guidance for CBD. The FDA issued the following statement regarding CBD:

"We have seen many CBD products being marketed with claims of therapeutic benefit, such as treating or curing serious diseases such as cancer and Alzheimer's disease, or other drug claims, without having gone through the drug approval process. The proliferation of such products may deter consumers from seeking proven, safe medical therapies for serious illnesses, potentially endangering their health or life.

We also have serious concerns about products that put the public at risk in other ways. For example, we are aware of the risks posed by product contaminants such as heavy metals, THC or other potentially harmful substances. We also have significant concerns about products marketed with false claims or statements such as omitted ingredients, incorrect statements about the amount of CBD, products marketed for use by vulnerable populations like children or infants, and products that otherwise put the public health at risk.

As we move forward, we are currently evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding factors the agency intends to take into account in prioritizing enforcement decisions. Any enforcement policy would need to further the goals of protecting the public and providing more clarity to industry and the public regarding the FDA's enforcement priorities while we take potential steps to establish a clear regulatory pathway."

https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market

See also: https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

Because guidance from the FDA is not yet final, the department recognizes the difficulty in regulating CBD by any agency. To allow providers adequate time to adjust, the department has amended the proposed rule to include a phase-in period. Additionally, the department has removed the requirement that the CBD be sourced

from Montana hemp and instead be sourced from hemp produced by a USDA-approved hemp production plant.

COMMENT #16: A commenter stated that DPHHS does not have rulemaking authority over the Department of Agriculture and hemp. Rulemaking authority comes from 50-46-344, MCA. This provision is limited to those areas expressly set forth in the MMA and does not reach the areas of products that do not contain medical marijuana.

RESPONSE #16: The department agrees that it does not have regulatory authority over the Montana Hemp Program. The department does have regulatory authority over medical marijuana providers. Pursuant to 50-46-344(1), MCA, "The department may adopt rules…to specify: (d) the security and operating requirements of dispensaries." The program is limited in its scope and serves medically fragile people who need products from safe supply lines.

COMMENT #17: A comment was received that without access to CBD, many people will be unable to obtain relief from their chronic conditions. Many people will be in a position of having no relief from their chronic conditions, increasing burden on the state and pushing people back towards opioids for relief. This feels like an extremely drastic step backwards, when you could simply require that testing results be made accessible to people purchasing CBD products.

RESPONSE #17: The department has amended the proposed rule to include a phase-in period and to allow CBD sourced from USDA-compliant suppliers. If providers are interested in producing CBD, providers can produce low THC, high CBD marijuana for cardholders. Those interested in CBD may obtain a medical marijuana card and participate in the program by purchasing tracked, tested, safe medical marijuana products.

COMMENT #18: One commenter stated that the department does not have the authority to prohibit the sale of hemp flower in medical marijuana dispensaries. They suggested that the department could use strip testing onsite to differentiate between marijuana and hemp.

RESPONSE #18: The department does have regulatory authority over medical marijuana providers. Field strip testing is not a practical option at this point. The department did discuss testing with the Department of Agriculture, and strip tests are both imprecise and extraordinarily expensive. The strip tests have a large margin of error that would not allow a tester to distinguish hemp from marijuana.

COMMENT #19: A provider submitted a comment that it is not always practical or safe for employees to wear their agent badges on the outermost portion of their clothing. This comment stated that even a clipped badge can get in the way of an employee's tasks. The provider also stated that it places an employee in danger if that employee is delivering marijuana to a cardholder; identifying that person as a marijuana employee puts the employee at risk for robbery.

RESPONSE #19: It is important for everyone to be able to immediately identify an individual as an employee of a medical marijuana dispensary. There are methods of fastening the badge in ways that allow it to be visible but out of an employee's way. Many business employees incur risk in the course of their employment and employers use many methods to increase safety and decrease risk.

COMMENT #20: A testing laboratory commented that the wording in ARM 37.107.128(3) was confusing because it did not specify that the amounts referred to THC and not to total amount of the product itself.

RESPONSE #20: The department agrees with this comment. The department amends the language specifying equivalency to reflect that amounts are of THC.

COMMENT #21: The department received numerous comments stating that the monthly and daily purchase amounts are arbitrary numbers that do not allow for adequate treatment of all ailments. It appears that the department is placing stricter rules on medical to shift everyone into the recreational market for the purpose of generating more tax revenue.

RESPONSE #21: The department disagrees with this comment. The five-ounce maximum purchase limit was established by the legislature and is set forth by statute, 50-46-319, MCA. The administrative rules cannot increase or change this amount. The department carefully researched appropriate amounts for those cardholders who submit a petition. The Colorado study upon which the department bases this rule is the most recent science it has obtained or received. The proposed increased amount allowed by an approved cardholder petition aligns with what other states allow.

COMMENT #22: A large number of comments asserted that the department should not rely on the Colorado study to set the MMP equivalencies.

RESPONSE #22: The Marijuana Equivalency in Portion and Dosage study referenced in this rulemaking process utilized data taken from 28,023 laboratory test samples. Senate Bill 265 established product testing standardization practices and placed oversite responsibility on the state laboratory, 50-46-304, MCA. While significant progress towards achieving the goal of standardized testing practices has been made, administrative rule changes to testing requirements were only finalized in October of 2019. Montana standardized testing data is in too early of a developmental stage to be used as a comparison to the Colorado study. No other peer-reviewed studies were submitted for department consideration.

COMMENT #23: One commenter suggested that the department use the physical equivalencies from the Colorado study to set equivalency amounts.

RESPONSE #23: As cited in the Colorado study, the dosing relationships between uptake methods can be quite different from the physical weight relationships. The

bioavailability of THC in delivery methods, pharmacokinetic effects, as well as the diverse and changing nature of products must be taken into consideration when determining equivalency.

COMMENT #24: Multiple commenters expressed concern that the proposed rule did not allow for sufficient amounts of marijuana-infused edible products.

RESPONSE #24: The proposed equivalencies allow for the purchase of 32 25mg edible products per day or 160 25mg edible products per month. With an approved petition to obtain 8 ounces of usable marijuana per month, a cardholder's monthly limit allows purchase of 256 25mg edible products per month.

COMMENT #25: A cardholder submitted a comment that he will not be able to obtain sufficient amounts of Rick Simpson Oil (RSO) under the equivalency for marijuana-infused edibles.

RESPONSE #25: The department classifies RSO as a concentrate. A cardholder may obtain 40 grams of RSO per month with a 5-ounce purchase limit and 64 grams per month with an approved petition for increase in monthly purchase limit.

COMMENT #26: A commenter stated that it is disproportional for a self-provider to legally possess 16 ounces of usable marijuana when all other cardholders may only purchase 5 ounces per month and may only possess one ounce at any point in time. Allowing a self-provider to possess 16 ounces encourages diversion.

RESPONSE #26: These differing amounts reflect the reality that harvesting a marijuana plant yields more than 5 ounces of usable marijuana. A self-provider may possess up to four flowering marijuana plants. Allowing a self-provider to possess 16 ounces provides relief from potential failed crops or other reasonable problems. Self-providers are not allowed to share their marijuana with anyone else, registered cardholders or otherwise. Any provider or cardholder who diverts marijuana is in violation of the law and subject to prosecution as well as revocation of their license and/or card.

COMMENT #27: A physician submitted a comment expressing concern about having physicians "prescribe" higher amounts than allowed by the rules. It is the physician's role to certify to the state and DPHHS that patients meet the medical indications for applying to the medical marijuana program. It is not a physician's role to prescribe marijuana to patients. Patients who think they need more than allowed by the rules should petition DPHHS directly.

RESPONSE #27: The department is aware of the federal case law that allows a physician to recommend that a patient use medical marijuana but prohibits a physician from prescribing it. Again, this is a legislative directive, codified by 50-46-319, MCA. Per statute, "A registered cardholder may petition the department for an exception to the monthly limit on purchases. The request must be accompanied by a confirmation from the physician who signed the cardholder's written certification

that the cardholder's debilitating medical condition warrants purchase of an amount exceeding the monthly limit." 50-46-319 (1)(d)(i), MCA. The physician does not "prescribe" any specific dosage. Rather, a physician "confirms" the registered cardholder's request.

COMMENT #28: A provider stated that providers who use a third-party vendor for tracking and point-of-sale cannot report to METRC instantly. For example, MJ Freeway only syncs with METRC every 15 minutes. MJ Freeway is a state-approved third-party software.

RESPONSE #28: This proposed rule meets the requirements of 50-46-304, MCA. A provider makes a business decision to use third-party software; it is not a state requirement to do so. In order to avoid sales that exceed statutory limits, the department must require that providers record sales in real time.

6. The department intends for the adoption and amendment of these rules to be retroactively effective to January 1, 2020.

/s/ Bree Gee
Bree Gee
Rule Reviewer

/s/ Sheila Hogan
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State May 5, 2020.