



MEDICAL MARIJUANA ACT: SUMMARY OF PROPOSED AND ADOPTED RULES

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Children, Families, Health, and Human Services Interim Committee

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BACKGROUND

Department of Public Health and Human Services authority to adopt rules that would put additional program requirements into place. The department proposed rules in November 2017 and adopted final rules on Feb. 9, 2018. The rules will go into effect April 10.

DPHHS changed a number of elements of the proposed rules after receiving public comment during the rulemaking process. This briefing paper discusses:

- elements of the medical marijuana program introduced through the new rules, rather than through explicit direction in either I-182 or SB 333;
- key changes between the proposed and adopted rules;
- key elements of the proposed rules that were adopted without changes; and
- the potential fiscal impact of the final rules.

It also includes information provided by DPHHS Operations Services Branch Manager Erica Johnston and Medical Marijuana Bureau Chief Darci Wiebe in a March 2 conversation.

Rules that Vary from or Expand on State Law

Either through language in the adopted rules or in the agency's response to public comment related to the rules, DPHHS has made changes not explicitly authorized in law but related to the general authority provided in 50-46-344, MCA, to adopt "other rules as necessary to implement the purposes of this part."

Phasing in Compliance

I-182 required providers of marijuana and marijuana-infused products to be licensed by, rather than registered with, the state. Both the initiative and SB 333 established new requirements for obtaining licenses, and the initiative made licensing effective on passage and approval of the law. Many changes in SB 333 related to licensing, inspections, and participation in a seed-to-sale tracking system were to be effective upon adoption of rules or no later than April 30, 2018.

However, in adopting the rules, DPHHS noted in its response to public comment that requiring cardholders and providers to be in compliance by April 30 "may cause problems." The department said it will instead require providers to obtain licenses when their current year-long registration is due to expire or by Dec. 31, 2018, whichever date is sooner.

DPHHS officials say that providers will not be able to use the inventory tracking system until they are licensed, but the agency will be issuing guidance noting that providers must comply with the labeling, signage, testing, and other requirements of the law until then and may be subject to inspection. Providers will be expected to keep manual records of their inventory and sales and would be able to become licensed before their registrations are due to expire, if they choose to do so.

Tracking Plants in the Seed-to-Sale System

SB 333 required the state to develop a system to track marijuana and marijuana-infused products “from either the seed or the immature plant stage” until the product is sold to a registered cardholder. The term “immature plant” is not defined in the Medical Marijuana Act or in administrative rule. The law defines a “mature” plant as one that is harvestable and flowering and defines a “seedling” as a nonflowering plant that is less than 12 inches tall.

The rules require providers to enter information into the tracking system when plants reach a height of 12 inches. However, DPHHS says the inventory tracking system will require that plants be entered into the system when they reach a height of 8 inches. DPHHS may revisit the administrative rule language that sets the 12-inch standard for tracking plants.

Measuring the Canopy Area

Until passage of SB 333, the number of mature plants and seedlings and the amount of usable marijuana that providers could possess was tied to the number of cardholders who had named them as providers. SB 333 removed that tie to the number of cardholders and instead allowed providers to have a “canopy allowed by the department.” The law defines canopy as “the total amount of square footage dedicated to live plant production at a registered premises consisting of the area of the floor, platform, or means of support or suspension of the plant.”

The rules continue to tie the number of plants to the number of cardholders by allowing providers and marijuana-infused products providers to have 50 square feet of canopy for each cardholder who has named them as a provider. The square footage is measured horizontally from the outermost point of the furthest mature flowering plant and around the outside of all mature plants located in the designated growing space; the rules do not address scenarios that might involve vertical stacking of plants within the same square footage, which was a subject of the House Taxation Committee’s discussion of the bill during the 2017 legislative session.

Requiring Employee Permits and Allowing Volunteer Labor

The law allows for licensed providers and testing labs to have employees. The rules require licensees to obtain and pay for a permit for each employee and to renew the permit annually. In response to public comment the department also decided to issue two “volunteer badges” to each provider. A volunteer may provide up to 300 hours of time each year but is not subject to the employee permit or fee or to other requirements related to employees.

Allowing Cardholder Use of Marijuana on Provider Premises

The Medical Marijuana Act prohibits the use of marijuana by a cardholder in plain view of the public or a place open to the general public. It does not specifically address the use of marijuana on provider or dispensary premises.

The proposed rules originally prohibited the use of intoxicants and the use of marijuana on provider premises. The final rule removed the prohibition on the use of intoxicants, and the department noted in its comments that it had removed the prohibition on marijuana use by active cardholders on registered premises. However, the requirement for a sign prohibiting marijuana consumption remained unchanged. DPHHS planned to publish a correction to that rule in March, to require signs to say that consumption is prohibited “except for registered cardholders.”

Statutory Requirements Not Addressed in Rule

The adopted rules do not address several areas of the law that called for DPHHS to set standards through administrative rules. Those areas are:

- how people applying to be providers from now through July 1, 2020, will prove that they have lived in Montana for at least three years or, if applying after that date, that they have resided in Montana for at least a year, as required by law;
- the type of equipment and instrumentation that testing laboratories must have;
- the insurance and bonding requirements for testing labs;
- the programs that DPHHS will accept as proof of a lab’s proficiency;
- the level of insects that marijuana and infused products may contain; and
- the amount of usable marijuana that cardholders who share a residence may possess if they are growing their own marijuana.

DPHHS is planning to issue further guidance on proof of provider residency; lab equipment, instrumentation, and proficiency programs; and acceptable levels of mold and insects. It may consult with the program’s attorney to determine if additional rules are needed on the allowable amounts of usable marijuana that cardholders may possess when they share a residence and are growing marijuana themselves.

Rules Adopted with Changes

Topic	Proposed Rule	Final Rule
Employee Requirements	<ul style="list-style-type: none"> • Permit needed for each employee of a licensee • Each employee must undergo a fingerprint background check • Employees may not have a drug offense • Annual permit fee of \$50 per employee 	<ul style="list-style-type: none"> • Permit still required • Fingerprint background check requirement removed • Prohibition on drug offenses removed • Annual fee reduced to \$10 • Providers also will receive two “volunteer badges” to be used for up to 300 hours per volunteer per year;
Premises Requirements	<ul style="list-style-type: none"> • Employees must wear a badge or clothing that identifies them as an employee • No minors allowed on premises • Consumption of marijuana and intoxicants on premises prohibited 	<ul style="list-style-type: none"> • Employees must wear a DPHHS-issued badge • Minors are allowed on premises if accompanied by an adult • Prohibition on intoxicant consumption removed; on-site consumption of marijuana by cardholders will be allowed
Labeling	<ul style="list-style-type: none"> • Labels must indicate amount suggested for use at any one time • Labels may not be attractive to children 	<ul style="list-style-type: none"> • Requirement to indicate amount to be used removed • “Attractive to children” specifically defined and includes the use of cartoon images and images of children, celebrities, or symbols commonly used to market products to children
Testing Requirements	<ul style="list-style-type: none"> • Required testing for numerous items, including heavy metals 	<ul style="list-style-type: none"> • Testing for heavy metals will be done at random • Number of pesticides to be tested for reduced from 60 to 19
Tracking System	<ul style="list-style-type: none"> • Licensees may not transport marijuana to another registered premises if the tracking system is not operating 	<ul style="list-style-type: none"> • Licensees allowed to transport to another registered premises when system is down
Transportation of Marijuana	<ul style="list-style-type: none"> • Licensees and their employees may transport marijuana only between a registered premises or testing laboratory 	<ul style="list-style-type: none"> • Licensees and their employees also may transport marijuana to a registered cardholder’s home
Financial Interest in Businesses	<ul style="list-style-type: none"> • Anyone holding a financial interest of 10% or more in the business must be included on a license application and meet licensing requirements 	<ul style="list-style-type: none"> • Anyone with a financial interest of any amount in a business must be included on a license application and meet licensing requirements
Fees	<ul style="list-style-type: none"> • Provider fees set at \$1,000 for providers with 10 or fewer cardholders and \$5,000 for providers with more than 10 cardholders, as established in 50-46-344, MCA • Cardholders must pay a \$10 fee to change providers 	<ul style="list-style-type: none"> • A new licensing level created for providers with 11 to 49 cardholders, with a fee of \$2,500 • Fee for changing a registry identification card removed • New licensing category created for caretaker relative, custodial parent, or legal guardian, with a fee of \$100
Licensing	<ul style="list-style-type: none"> • Implementation schedule not addressed 	<ul style="list-style-type: none"> • Licensing will be staggered over time as current provider registrations are up for renewal

Rules Adopted Without Changes

Topic	Final Rule
Premises Requirements	<ul style="list-style-type: none"> • Written security plan must safeguard against theft, diversion, or tampering of items • Written operating procedures must address pesticide use, water usage, and waste disposal • Drive-up windows are prohibited
Licensee Possession Limits	<ul style="list-style-type: none"> • Providers may have 50 square feet of canopy space per registered cardholder; canopy is measured horizontally from the outermost point of the furthest mature flowering plant around all of the mature flowering plants in designated growing space • A provider may designate multiple grow canopy areas at a registered premises but the spaces must be separated by a physical boundary or at least 8 feet of open space
Extracts	<ul style="list-style-type: none"> • Local fire officials must approve equipment and facilities used to process extracts • Licensees with chemical manufacturing endorsements may not use certain types of solvents and fuels
Labeling and Packaging	<ul style="list-style-type: none"> • All marijuana must list the date of harvest or manufacture, net weight or volume, strain of marijuana, and concentration by weight or volume of THC, THCA, CBD, and CBDA • Labels must contain certain warnings, ingredient and testing information, and indicate that the product should be kept out of reach of children • Packaging must be child resistant
Testing Requirements	<ul style="list-style-type: none"> • Licensees with more than 10 registered cardholders must test each harvest of marijuana or process lot of infused products or extracts with a licensed testing laboratory before selling or transferring the products • DPHHS may require licensees to recall items for public health or safety reasons
Tracking System	<ul style="list-style-type: none"> • All licensees must participate in an inventory tracking system that tracks all plants 12 inches or taller through production to final sale • A licensee who loses access to the tracking system must maintain records of tracking activities and enter the information into the system when access is restored • All on-premises and in-transit inventories must be reconciled in the system at the close of business each day • A receiving location must document in the tracking system all marijuana items received and any differences between the quantity specified in the transport manifest and the quantity received
Inspections	<ul style="list-style-type: none"> • DPHHS may inspect licensees upon initial application, annual renewal, at random, and based on complaints

Fiscal Impact

SB 333 set fees for providers with 10 or fewer registered cardholders at \$1,000 a year and at \$5,000 for providers with more than 10 cardholders. The law allowed DPHHS to set fees for testing laboratories, dispensaries, and chemical manufacturing endorsements by rule. The law also gave DPHHS authority to revise the provider fee “as needed to adequately fund the administration of the Montana Medical Marijuana Act and the seed-to-sale tracking system, including operating reserve funds of \$250,000.”

In its amended and final rules, DPHHS created a new licensing tier for providers with 11 to 49 cardholders. The agency set the license fee at \$2,500 for those providers.

The final rules also:

- reduced the proposed fee for employee permits from \$50 to \$10;
- eliminated the proposed fee for registered cardholders who change providers; and
- created a new fee of \$100 for legal guardians, caretaker custodial parents, and caretaker relatives who serve as a provider for a minor or another family member, so those individuals don't have to pay the \$1,000 provider fee. DPHHS says the caretaker relative must live with the family member, but the requirement is not in rule.

DPHHS originally estimated that the new fees for providers, cardholders, testing labs, employees, dispensaries, change requests, and chemical endorsements would bring in nearly \$2.4 million, compared with the \$131,000 raised by the \$5 fee that is currently charged to obtain a registry identification card and the \$50 fee for providers. The revised fees will raise about \$1.8 million, or about \$550,000 less than the originally proposed fees would have raised. . DPHHS believes the revenue generated will cover the program costs and allow for the required reserve. The agency will review costs and revenues annually and adjust fees if necessary.

The table below shows the differences in estimated collections. The revised rules did not contain a revised fiscal impact; the calculations below were based on numbers DPHHS used for the original fiscal impact and on registry statistics for October 2017, the same time period used for the original estimate.

Category	Number	Proposed Fee	Final Fee	Proposed Total	Final Total
Cardholders	20,000	\$30	\$30	\$600,000	\$600,000
Providers with 10 or Fewer Cardholders	387	\$1,000	\$1,000	\$387,000	\$387,000
Providers with 11 to 49 Cardholders	184	\$5,000	\$2,500	\$920,000	\$460,000
Providers with 50 or More Cardholders	48	\$5,000	\$5,000	\$240,000	\$240,000
Testing Laboratories	4	\$2,000	\$2,000	\$8,000	\$8,000
Dispensaries	100	\$500	\$500	\$50,000	\$50,000
Chemical Manufacturing Endorsements	137	\$500	\$500	\$68,500	\$68,500
Employee Permits	1,400	\$50	\$10	\$70,000	\$14,000
Change Requests	4,000	\$10	\$0	\$40,000	\$0
Parent/Guardian/Relative Providers	10	--	\$100	--	\$1,000
Total				\$2,383,500	\$1,828,500