

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

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| In the matter of the adoption of New Rules I through XX, the amendment of ARM 37.107.110, 37.107.111, 37.107.115, 37.107.117, 37.107.119, 37.107.127, and 37.107.128 and the repeal of ARM 37.107.113, 37.107.116, 37.107.121, 37.107.123, 37.107.125, 37.107.129, 37.107.132, 37.107.133, 37.107.135 pertaining to the Montana medical marijuana program |) | NOTICE OF ADOPTION, AMENDMENT, AND REPEAL |
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TO: All Concerned Persons

1. On November 9, 2017, the Department of Public Health and Human Services published MAR Notice No. 37-820 pertaining to the public hearing on the proposed adoption, amendment, and repeal of the above-stated rules at page 2037 of the 2017 Montana Administrative Register, Issue Number 21.

2. The department has adopted the following rules as proposed: New Rule I (37.107.102), New Rule II (37.107.130), New Rule IV (37.107.105), New Rule IX (37.107.405), New Rule XI (37.107.410), New Rule XV (37.107.206), New Rule XVIII (37.107.420), New Rule XIX (37.107.415), and New Rule XX (37.107.425). The department has amended the following rules as proposed: ARM 37.107.111, 37.107.127, and 37.107.128. The department has repealed the following rules as proposed: ARM 37.107.113, 37.107.116, 37.107.121, 37.107.123, 37.107.125, 37.107.129, 37.107.132, 37.107.133, 37.107.135.

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

NEW RULE III (37.107.120) MARIJUANA EMPLOYEE PERMIT

(1) and (2) remain as proposed.

(3) ~~A marijuana employee permit will not be issued to any individual that has been convicted of a drug offense~~ The department will issue providers two department-issued volunteer badges to be used for no more than 300 hours per volunteer per year.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-311, MCA

NEW RULE V (37.107.118) MARIJUANA AND MARIJUANA-INFUSED PRODUCTS PROVIDER LICENSEE REQUIREMENTS (1) remains as proposed.

(2) All licensee employees must wear a department-issued identification badge or clothing that easily identifies the individual as an employee.

(3) A licensee must maintain a daily log of all visitor activity ~~to a limited access area~~ on a registered premises. The log must contain the visitor's first and last name and date of visit.

(4) remains as proposed.

(5) A licensee must post signs inside the registered premises in a conspicuous location ~~where the signs can be easily read by individuals on the registered premises~~ that read:

(a) "No Minors Permitted Anywhere on This Premises Except When Accompanied By An Adult"; and

(b) "No On-Site Consumption of Marijuana"; and.

~~(c) At all areas of ingress or egress to a limited access area a sign that reads: "Do Not Enter – Limited Access Area – Access Limited to Authorized Personnel and Escorted Visitors."~~

(6) A licensee may have up to 50 square feet of canopy space per registered cardholder:

(a) remains as proposed.

(b) a licensee may designate multiple grow canopy areas at a registered premises but those spaces must be separated by a physical boundary such as an interior wall or by at least eight feet of open space;

(c) through (7) remain as proposed.

(8) A licensee must have a written security plan maintained on the registered premises that adequately safeguards against theft, diversion, or tampering of marijuana items both on the registered premises and during transit.

(9) remains as proposed.

(10) A licensee must ensure general sanitary requirements are met on a registered premises to include:

(a) ~~adequate and convenient~~ hand-washing facilities;

(b) proper and timely removal of all litter and waste; and

(c) ~~adequate and readily accessible~~ toilet facilities that are maintained in a sanitary condition and good repair; and

~~(d) prohibiting a licensee or licensee employee with a communicable disease, open or draining skin lesions, or any illness accompanied by diarrhea or vomiting from working on a registered premises until the condition is corrected if the individual has a reasonable possibility of contacting marijuana items; and~~

~~(e) licensee or licensee employees wash hands thoroughly before starting work, prior to having contact with a marijuana item, and at any other time when the hands may have become soiled or contaminated.~~

~~(11) On-site consumption of intoxicants by any individual is strictly prohibited.~~

(12) through (19) remain as proposed but are renumbered (11) through (18).

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

NEW RULE VI (37.107.204) PRODUCING MARIJUANA-INFUSED PRODUCTS, CONCENTRATES, AND EXTRACTS (1) remains as proposed.

(2) A licensee with a chemical manufacturing endorsement must:

(a) only use hydrocarbon-based solvents that are at least 99 percent ~~purity~~ pure, except when using solvents outlined in (3);

(b) through (5) remain as proposed.

(6) All licensees using solvent-based or solvent-free extraction processes authorized under this rule must obtain a chemical manufacturing endorsement.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-312, 50-46-328, 50-46-329, 50-46-330, MCA

NEW RULE VII (37.107.401) LABELING OF MARIJUANA ITEMS (1) Prior to marijuana items being sold or transferred to a registered cardholder the container holding the usable marijuana items must have a label that has the following information:

(a) through (d) remain as proposed.

(e) concentration by weight or volume of THC, THCA, CBD, and CBDA; and
(f) ~~amount suggested for use by the registered cardholder at any one time;~~

and

(g) remains as proposed but is renumbered (f).

(2) through (10) remain as proposed.

(11) A label may not:

(a) remain as proposed.

(b) be attractive to minors. For the purpose of this rule, "attractive to minors" means packaging, labeling and marketing that features:

(i) cartoons;

(ii) designs, brands, or names that resemble a non-cannabis consumer product of the type that is typically marketed to minors;

(iii) symbols or celebrities that are commonly used to market products to minors;

(iv) images of minors; or

(v) words that refer to products that are commonly associated with minors or marketed by minors.

(12) and (13) remain as proposed.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-326, MCA

NEW RULE VIII (37.107.402) PACKAGING FOR SALE TO CONSUMER

(1) remains as proposed.

(2) Marijuana items for final sale to a consumer must be:

(a) packaged in a container that is child-resistant ~~as certified by a qualified third-party child-resistant package testing firm; or~~

~~(b) placed within an exit package that is certified by a qualified third-party child-resistant package testing firm prior to final sale to consumer; and~~

~~(c) packaged in a container or placed in an exit package that is capable of being resealed and made child resistant again after it has been opened if the item is designed for multiple use as defined in ARM 37.107.110; and~~

(d) remains as proposed, but is renumbered (b).

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-326, MCA

NEW RULE X (37.107.407) QUALITY ASSURANCE TESTING REQUIREMENTS (1) Except as provided in (10), A a licensee must submit for testing every test batch from a harvest lot of marijuana and process lots of marijuana-infused product, extracts, and concentrates intended for use by a registered cardholder prior to selling or transferring the marijuana item to a registered cardholder.

(2) Usable marijuana lots consisting of dried leaves and flowers must be tested for the following:

(a) through (c) remain as proposed.

(d) microbiological screening; and

~~(e) heavy metals screening; and~~

(f) remains as proposed, but is renumbered (e).

(3) Marijuana concentrate and extract lots must be tested for the following:

(a) and (b) remain as proposed.

~~(c) heavy metals screening;~~

(d) and (e) remain as proposed, but are renumbered (c) and (d).

(4) and (5) remain as proposed.

(6) The sample and related lot or test batch fail quality assurance testing for moisture analysis if the results exceed the following limits:

~~(a) water activity rate of more than 0.65 a_w ; and~~

~~(b) (a) moisture content no more than ~~fifteen~~ twelve percent.~~

(7) The sample and related lot or test batch fail quality assurance testing for foreign matter screening if the results exceed the following limits:

(a) ~~two~~ five percent of stems 3mm or more in diameter; and

(b) ~~five~~ two percent of seeds or other foreign matter.

(8) and (9) remain as proposed.

(10) Heavy metals will be tested at random. A sample and related lot or test batch fail quality assurance testing for heavy metals if the results exceed the limits provided in the table below.

| Heavy Metals | | |
|-------------------|--------------------------------------|-----------------------------|
| | Limits; Unprocessed/Dry Flower | Limits; Extract |
| Inorganic arsenic | 2.0 µg/g | 4 <u>10</u> µg/g |
| Cadmium | 0.82 µg/g | 4.1 µg/g |
| Lead | 1.2 µg/g | 6.0 µg/g |

| | | |
|---------|----------|----------|
| Mercury | 0.4 µg/g | 2.0 µg/g |
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(11) A sample and related lot or test batch fail quality assurance testing for pesticides if the results exceed the limits provided in the table below.

| Pesticides | | | |
|----------------------|--------------------------------------------------|------------------------------------------|---------------------------|
| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm; Unprocessed/Dry Flower | Action Level ppm; Extract |
| Abamectin | 71751-41-2 | 0.5 | 2.5 |
| Acephate | 30560-19-4 | 0.4 | 2 |
| Acequinocyl | 57960-19-7 | 2 | 10 |
| Acetamiprid | 135410-20-7 | 0.2 | 4 |
| Aldicarb | 116-06-3 | 0.4 | 2 |
| Azoxystrobin | 131860-33-8 | 0.2 | 4 |
| Bifenazate | 149877-41-8 | 0.2 | 1 |
| Bifenthrin | 82657-04-3 | 0.2 | 1 |
| Boscalid | 188425-85-6 | 0.4 | 2 |
| Carbaryl | 63-25-2 | 0.2 | 4 |
| Carbofuran | 1563-66-2 | 0.2 | 4 |
| Chlorantraniliprole | 500008-45-7 | 0.2 | 4 |
| Chlorfenapyr | 122453-73-0 | 4 | 5 |
| Chlormequat chloride | 999-81-5 | 1 | 5 |
| Chlorpyrifos | 2921-88-2 | 0.2 | 4 |
| Clofentezine | 74115-24-5 | 0.2 | 4 |
| Cyfluthrin | 68359-37-5 | 1 | 5 |
| Cypermethrin | 52315-07-8 | 4 | 5 |
| Daminozide | 1596-84-5 | 1 | 5 |
| DDVP (Dichlorvos) | 62-73-7 | 0.1 | 0.5 |
| Diazinon | 333-41-5 | 0.2 | 4 |
| Dimethoate | 60-51-5 | 0.2 | 4 |
| Ethoprophos | 13194-48-4 | 0.2 | 4 |
| Etofenprox | 80844-07-4 | 0.4 | 2 |
| Etoxazole | 153233-91-1 | 0.2 | 1 |
| Fenoxycarb | 72490-01-8 | 0.2 | 1 |
| Fenpyroximate | 134098-61-6 | 0.4 | 2 |
| Fipronil | 120068-37-3 | 0.4 | 2 |
| Fonicamid | 158062-67-0 | 4 | 5 |
| Fludioxonil | 131341-86-4 | 0.4 | 2 |

| | | | |
|--------------------|-----------------------|-----|-----|
| Hexythiazox | 78587-05-0 | 1 | 5 |
| Imazalil | 35554-44-0 | 0.2 | 1 |
| Imidacloprid | 138261-41-3 | 0.4 | 2 |
| Kresoxim-methyl | 143390-89-0 | 0.4 | 2 |
| Malathion | 121-75-5 | 0.2 | 1 |
| Metalaxyl | 57837-19-1 | 0.2 | 1 |
| Methiocarb | 2032-65-7 | 0.2 | 1 |
| Methomyl | 16752-77-5 | 0.4 | 2 |
| Methyl parathion | 298-00-0 | 0.2 | 1 |
| MGK-264 | 113-48-4 | 0.2 | 1 |
| Myclobutanil | 88671-89-0 | 0.2 | 0.6 |
| Naled | 300-76-5 | 0.5 | 2.5 |
| Oxamyl | 23135-22-0 | 1 | 5 |
| Paclobutrazol | 76738-62-0 | 0.4 | 2 |
| Permethrins* | 52645-53-1 | 0.2 | 1 |
| Phosmet | 732-11-6 | 0.2 | 1 |
| Piperonyl_butoxide | 51-03-6 | 2 | 10 |
| Prallethrin | 23031-36-9 | 0.2 | 1 |
| Propiconazole | 60207-90-1 | 0.4 | 2 |
| Propoxur | 114-26-1 | 0.2 | 1 |
| Pyrethrins† | 8003-34-7 | 1 | 5 |
| Pyridaben | 96489-71-3 | 0.2 | 1 |
| Spinosad | 168316-95-8 | 0.2 | 1 |
| Spiromesifen | 283594-90-1 | 0.2 | 1 |
| Spirotetramat | 203313-25-1 | 0.2 | 1 |
| Spiroxamine | 118134-30-8 | 0.4 | 2 |
| Tebuconazole | 80443-41-0 | 0.4 | 2 |
| Thiacloprid | 111988-49-9 | 0.2 | 1 |
| Thiamethoxam | 153719-23-4 | 0.2 | 1 |
| Trifloxystrobin | 141517-21-7 | 0.2 | 1 |

* Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-311, 50-46-326, MCA

NEW RULE XII (37.107.305) MARIJUANA TESTING LABORATORY LICENSEE REQUIREMENTS (1) through (4) remain as proposed.

(5) All licensee employees must wear a department-issued identification badge ~~or clothing that easily identifies the individual as an employee.~~

(6) A licensee must maintain a daily log of all visitor activity ~~to a limited access area~~ on a registered premises. The log must contain the first and last name and the date they visited.

(7) and (8) remain as proposed.

(9) A licensee must have a written security plan maintained on the premises that ~~adequately~~ safeguards against theft, diversion, or tampering of marijuana items both on the premises and during transit.

(10) remains as proposed.

(11) A licensee must ensure general sanitary requirements are met on the premises to include:

(a) ~~adequate and convenient~~ hand-washing facilities;

(b) proper and timely removal of all litter and waste; and

(c) ~~adequate and readily accessible~~ toilet facilities that are maintained in a sanitary condition and good repair;

(d) ~~prohibiting a licensee or licensee employee with a communicable disease, open or draining skin lesions, or any illness accompanied by diarrhea or vomiting from working on a premises until the condition is corrected if the individual has a reasonable possibility of contacting marijuana items; and~~

(e) ~~assurance that the licensee or licensee employees wash hands thoroughly before starting work, prior to having contact with a marijuana item, and at any other time when the hands may have become soiled or contaminated.~~

(12) through (14) remain as proposed.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-311, 50-46-312, 50-46-326, 50-46-328, 50-46-329, MCA

NEW RULE XIII (37.107.306) MARIJUANA TESTING LABORATORIES ACCREDITATION (1) A laboratory licensee must ~~be~~ have processes that are ISO 17025 accredited.

(2) An applicant, after providing written evidence of pending ISO 17025 accreditation:

(a) remains as proposed.

(b) is eligible for a provisional license not to exceed ~~six~~ 12 months.

(3) A licensed laboratory must maintain ISO accreditation at all times.

(4) If a laboratory's process accreditation lapses or is revoked, the laboratory may not perform any activities until it is reinstated.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-311, 50-46-312, MCA

NEW RULE XIV (37.107.205) INVENTORY TRACKING SYSTEM USER REQUIREMENTS (1) A licensee must have ~~an~~ a department inventory tracking system account activated and functional prior to operating or exercising any privileges of the license and must maintain an active account while licensed.

(2) through (13) remain as proposed.

~~(14) A licensee may not transport any marijuana items to another registered premises until access is restored and all information is recorded into the inventory tracking system.~~

(15) remains as proposed, but is renumbered (14).

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-311, 50-46-319, 50-46-326, 50-46-329, MCA

NEW RULE XVI (37.107.124) TRANSPORTATION AND DELIVERY OF MARIJUANA ITEMS (1) Marijuana items may only be transported between a registered premises, or licensed testing laboratories, or a registered cardholder's home by a licensee or licensee employee.

(2) through (10) remain as proposed.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-311, 50-46-319, 50-46-326, 50-46-329, MCA

NEW RULE XVII (37.107.413) WASTE MANAGEMENT

(1) and (2) remain as proposed.

(3) The allowable method to render marijuana plant waste unusable is by grinding and incorporating the marijuana plant waste with other ground materials so the resulting mixture is at least fifty percent nonmarijuana waste by volume. Material used to grind with the marijuana falls into two categories: compostable waste and noncompostable waste.

(a) Compostable mixed waste is marijuana waste to be disposed as compost feedstock or in another organic waste method, such as an anaerobic digester, mixed with food waste, yard waste, or vegetable based grease or oils.

(b) Noncompostable mixed waste is marijuana waste to be disposed in a landfill or another disposal method, such as an incinerator, mixed with paper waste, cardboard waste, plastic waste, or soil.

(3) through (5) remain as proposed, but are renumbered (4) through (6).

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-311, 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:

37.107.110 DEFINITIONS (1) and (2) remain as proposed.

(3) "Batch" means:

(a) a quantity of usable marijuana from a harvest lot; or

(b) a quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.

(3) and (4) remain as proposed, but are renumbered (4) and (5).

(6) "Child resistant" means designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use

properly. The standard for child-resistant packaging is set by the federal consumer product safety commission (CPSC) and the testing procedures found in 16 CFR 1700.20 (2012).

(5) through (8) remain as proposed, but are renumbered (7) through (10).

(11) "Financial interest" means any interest or ownership in the business or entity.

(9) and (10) remain as proposed, but are renumbered (12) and (13).

~~(14)~~ (14) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 48 72 hour period at the same location, and cured under uniform conditions. A harvest lot may contain multiple strains.

(12) through (25) remain as proposed, but are renumbered (15) through (28).

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-307, 50-46-308, 50-46-310, 50-46-318, 50-46-344, MCA

37.107.115 LICENSE AND ENDORSEMENT APPLICATION PROCESS

(1) through (3) remain as proposed.

(4) Applicants include, but are not limited to:

(a) any individual or legal entity who holds or controls an interest, ownership, or partnership ~~of ten percent or more~~ in the business or entity;

(b) through (17) remain as proposed.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-309, 50-46-344, MCA

37.107.117 FEES (1) An applicant must submit to the department the following fees with the initial application and renewal application:

(a) remains as proposed.

(b) provider or marijuana-infused product provider with:

(i) ten or fewer registered cardholders, an application fee of \$1,000;

~~(c) (ii) provider or marijuana-infused product provider with more than ten~~ 11 to 49 registered cardholders, an application fee of \$5,000 \$2,500;

~~(d) a combined provider and marijuana-infused product provider with ten or fewer registered cardholders, an application fee of \$1,000;~~

(iii) 50 or more registered cardholders, an application fee of \$5,000.

(e) through (h) remain as proposed, but are renumbered (c) through (f).

~~(i)~~ (g) marijuana employee permit fee of \$50 \$10 for each individual licensee employee listed on application and any subsequent hires; or

~~(j) for amending or changing a registry identification card, a fee of \$10.~~

(h) a caretaker relative, caretaker custodial parent, or legal guardian provider fee of \$100.

(2) and (3) remain as proposed.

AUTH: 50-46-344, MCA

IMP: 50-46-344, MCA

37.107.119 FINGERPRINT AND BACKGROUND CHECK REQUIREMENTS

(1) A fingerprint background check by the Montana Department of Justice and Federal Bureau of Investigation is required for the following:

- (a) all individuals listed on the application; and
- ~~(b) employees defined in 50-46-302, MCA; and~~
- (c) remains as proposed, but is renumbered (b).

(2) through (4) remain as proposed.

(5) Results of background checks must be received prior to: approval of any application.

~~(a) approval of any application; and~~

~~(b) issuance of a marijuana employee permit.~~

(6) remains as proposed.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-307, 50-46-308, 50-46-311, 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: The department received many comments about employees including the employee badge, employee fingerprinting, employee clothing, volunteers, and employees with drug convictions, and related general sanitary requirements.

RESPONSE #1: The department agrees with the comments and revised New Rules III and XII to remove the requirement that employees will not be issued an employee permit if they have been convicted of a drug offense. The department also removed the requirement for employee fingerprinting in ARM 37.107.119. The department has also provided more clarification regarding volunteers. The department has also removed the requirement that employees have special clothing to identify them as an employee. The department revised general sanitary requirements. The department does not agree that employees do not need to have an employee permit. Issuing permits to all employees allows the department to effectively regulate the program.

COMMENT #2: The department received many comments concerning requirements for cardholder, provider, and testing laboratory applicant's proof of Montana residency.

RESPONSE #2: The department does not agree.

COMMENT #3: The department received many comments about licensee requirements including use of cannabis on a registered premises by cardholder, allowing minors on registered premises, requiring a badge and dress code, health and safety, signage, reporting registered premises changes, reporting operations plans, visitors logs, and canopy limits.

RESPONSE #3: The department agrees with the comments regarding use of cannabis on a registered premises by cardholders, minors on registered premises, and requiring a badge and dress code. The department has revised New Rule V to allow for cannabis use on registered premises by active cardholders. The department has also revised New Rule V to allow minors on registered premises when accompanied by an adult. The department further recognizes that many providers work from their residence and has removed the prohibition of on-site consumption of intoxicants. Badge and dress code comments are addressed in response #1. The department does not agree with the comments regarding safety requirements, excess signage, reporting registered premises changes, reporting operations plans, visitors logs, and canopy limits. These rules ensure the health and safety of providers, employees, cardholders, and visitors and allows the department to effectively regulate the program.

COMMENT #4: The department received several comments about labeling of marijuana items, language content, and packaging.

RESPONSE #4: The department disagrees that requiring all the information to be on the product label is excessive. Consistent and complete labeling ensures patient safety and encourages safe consumption of medicine. The department agrees with the comments regarding the attractive to minors labeling requirement and packaging, and has provided additional clarity in New Rules VII, VIII, and related definitions.

COMMENT #5: The department received many comments about harvest and process lot definition, frequency of testing, quality assurance testing protocols, random testing, and testing costs. There were also comments concerning errors in actual testing values for inorganic arsenic.

RESPONSE #5: The department agrees with many of the comments and has revised New Rule X to decrease the number of required pesticides for testing and to allow for random testing of heavy metals. The reduced testing requirements will decrease the cost burden to small providers and still provide safe medicine for patients. The department has corrected the testing value error for inorganic arsenic.

COMMENT #6: The department received several comments about test process accreditation and ISO certification.

RESPONSE #6: The department agrees with the comments and has revised New Rule XIII to correct that a process is certified not a lab and to allow sufficient time to acquire ISO certification.

COMMENT #7: The department received several comments about patient home delivery.

RESPONSE #7: The department agrees with the comments and has revised New Rule XVI to include patient home delivery.

COMMENT #8: The department received several comments about clarifying waste management.

RESPONSE #8: The department agrees with the comments and has clarified waste management for compostable and noncompostable waste in New Rule XVII. The department does not agree that storing waste for 72 hours is excessive.

COMMENT #9: The department received comments related to clarification of reporting requirements by cardholders and licensees.

RESPONSE #9: The department disagrees that any of the reporting requirements are excessive. The department refers the commenters to the department's response #3.

COMMENT #10: The department received several comments about inspections criteria and the consequences of failed inspections.

RESPONSE #10: The department agrees that inspection criteria needs to be available to providers and will provide guidelines for interpreting the rules in the form of survey tools on our website prior to implementing inspections. The department does not agree that failed inspections are not adequately addressed in New Rule XX, as proposed.

COMMENT #11: The department received comments about fees for licensing, cardholders, employees, caretaker or legal guardians, and change fees.

RESPONSE #11: The department agrees with the comments related to employee permit fees, fees to change providers, and licensing fees including caretaker or legal guardians, and has revised its amendments to ARM 37.107.117 upon adoption. The department does not agree that the fees are excessive as fees are used to offset the costs of running the program in accordance with Montana Medical Marijuana Act.

COMMENT #12: The department received comments about clarification of various proposed definitions including financial interest, employee, registered premises, batch, and process lot.

RESPONSE #12: The department agrees with the comments provided and has revised ARM 37.107.115 to clarify who holds or controls an interest, ownership, or partnership in the business or entity. The department also revised definitions in ARM 37.107.110 to include definitions for batch, financial interest, harvest lot, and process lot.

COMMENT #13: The department received comments about transitional time frames.

RESPONSE #13: The department agrees that requiring cardholders and providers to be in compliance on April 30, 2018 may cause problems. The department will now require cardholders and providers to license at their annual registration renewal or by December 31, 2018, whichever is sooner.

COMMENT #14: The department received several comments concerning the significant financial impact of these rules on small businesses.

RESPONSE #14: The department disagrees that the adoption of proposed new rules, amendments to existing rules, and the repeal of certain existing rules, create a significant financial impact to small businesses. The new requirements and any financial or increased regulatory impact are a result of statutory requirements, not of the rules.

COMMENT #15: The department received several comments related to mechanical extractions.

RESPONSE #15: The department has clarified in New Rule VI that all solvent and non-solvent extractors must obtain a chemical manufacturing endorsement.

COMMENT #16: The department received comments about inventory tracking system access issues relating to power outages.

RESPONSE #16: The department revised New Rule XIV to allow for business to continue in such circumstances.

COMMENT #17: The department received many comments relating to statutory provisions, existing rules not currently subject to amendment, over-regulation, taxation, advertising, choice of inventory tracking system and user requirements, and desired protection from federal law.

RESPONSE #17: While the department appreciates these comments, they are outside of the scope of this rulemaking.

6. The department intends to make these rules effective April 10, 2018.

/s/ Flint Murfitt
Flint Murfitt, Attorney
Rule Reviewer

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

Certified to the Secretary of State January 30, 2018.