

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

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 PUBLIC HEARING ON PROPOSED ADOPTION, AMENDMENT, AND REPEAL

TO: All Concerned Persons

1. On November 30, 2017, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption, amendment, repeal of the above-stated rule.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on November 13, 2017, to advise us of the nature of the accommodation that you need. Please contact Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I PURPOSE (1) The purpose of these rules is to establish requirements for implementing the Montana Medical Marijuana Act. These rules outline requirements for registered cardholders, providers, marijuana-infused product providers, dispensaries, chemical manufacturing endorsements, marijuana quality assurance testing, testing laboratories, and inventory tracking system.

AUTH: 50-46-344, MCA
IMP: 50-46-301, 50-46-303, MCA

NEW RULE II DENIAL OR REVOCATION OF APPLICATION, LICENSE, OR ENDORSEMENT (1) The department, after written notice to the applicant or licensee, may deny or revoke an application, license, or endorsement if:

- (a) the applicant did not provide the information required in the application;
 - (b) the department determines the information provided in the application was inaccurate, misleading, or falsified;
 - (c) the applicant did not submit the required fee with application;
 - (d) the applicant is not a resident of the State of Montana as defined in 1-1-215, MCA;
 - (e) the department is notified in writing by a landlord revoking permission under 50-46-308, MCA;
 - (f) the applicant or licensee is found to be in violation of 50-46-308, 50-46-311, and 50-46-312, MCA;
 - (g) a provider or marijuana-infused product provider has been convicted of driving under the influence of alcohol or drugs under 50-46-320, MCA;
 - (h) a provider or marijuana-infused product provider is found to be in violation of 50-46-320(8), MCA;
 - (i) the applicant or licensee is found to be in violation of 50-46-330, MCA;
 - (j) the applicant or licensee did not report changes to the department in accordance with [NEW RULE XIX];
 - (k) the licensee is no longer named as a provider or marijuana-infused product provider by a registered cardholder;
 - (l) the applicant is not in substantial compliance with any other licensing requirements established by this chapter; or
 - (m) the applicant or licensee is found to be in violation of any provision under Title 50, chapter 46, part 3, MCA.
- (2) Any denial or revocation under this part is subject to judicial review.
- (3) A person whose application has been denied or a current licensee whose license has been revoked may not reapply for at least six months from the date of denial or revocation.

AUTH: 50-46-344, MCA

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

NEW RULE III MARIJUANA EMPLOYEE PERMIT (1) A marijuana employee permit is required for any employee of a licensee prior to working.

(2) The marijuana employee permit must always be carried when performing work on behalf of a licensee.

(3) A marijuana employee permit will not be issued to any individual that has been convicted of a drug offense.

AUTH: 50-46-344, MCA

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

NEW RULE IV PROOF OF MONTANA RESIDENCY (1) If an applicant does not have a valid Montana driver license or Montana identification card, the applicant must submit documentation that shows the applicant is a resident of Montana, such as a current lease agreement or current utility bill that has the applicant's name and address.

(2) Montana residency must be maintained by registered cardholders and licensees.

AUTH: 50-46-344, MCA

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

NEW RULE V MARIJUANA AND MARIJUANA-INFUSED PRODUCTS PROVIDER LICENSEE REQUIREMENTS (1) A licensee must clearly identify all limited access areas at a registered premises.

(2) All licensee employees must wear a 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) Visitors must be accompanied by a licensee or licensee employee at all times.

(5) A licensee must post signs 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";

(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 50 square feet of canopy space per registered cardholder:

(a) square footage of canopy space is measured horizontally starting from the outermost point of the furthest mature flowering plant in a designated growing space and continuing around the outside of all mature flowering plants located within the designated growing space;

(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) total canopy size is calculated by multiplying 50 square feet of canopy by the number of registered cardholders; and

(d) a licensee must not exceed the total canopy allowed by the department for cultivation of marijuana.

(7) A licensee is responsible for the security of all marijuana items on a registered premises, in transit, and under the supervision of any licensee or licensee employee until the marijuana item is sold.

(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) Commercial grade, nonresidential door locks must be installed on every external door and gate of a registered premises.

(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;
 - (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 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) A licensee must establish written standard operating procedures to produce marijuana and maintain them on the registered premises. The standard operating procedures must include:
- (a) when and how all pesticides or other chemicals are to be applied during the production process;
 - (b) water usage and waste water disposal;
 - (c) the waste disposal plan; and
 - (d) any other written procedures as required by the department.
- (13) If a licensee makes a material change to its standard operating procedures it must document the change and revise its standard operating procedures accordingly.
- (14) A licensee must use a standardized scale whenever marijuana items are:
- (a) packaged for sale by weight;
 - (b) bought and sold by weight; and
 - (c) weighed for entry into the inventory tracking system.
- (15) A licensee must maintain the following records in either paper or electronic form on the registered premises for at least three years:
- (a) financial records that clearly reflect all financial transactions; and
 - (b) all licensee employee training and payroll records.
- (16) A licensee must establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergency at all registered premises.
- (17) In addition to other records required by these rules, a licensee must maintain on the registered premises:
- (a) the material safety data sheet for all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana;
 - (b) the original label or a copy thereof for all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana; and
 - (c) a log of all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana.
- (18) The licensee must maintain documentation of meeting all local jurisdiction requirements such as licensing, fire, health, and safety.
- (19) A licensee may not:
- (a) give marijuana items as a prize, premium or consideration for a lottery, contest, game of chance or game of skill, or competition of any kind;

(b) sell or transfer to a registered cardholder any marijuana item through a drive-up window; or

(c) treat or otherwise alter usable marijuana, consisting of dried leaves and flowers, with the intent of altering the color, appearance, weight, or smell.

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 PRODUCING MARIJUANA-INFUSED PRODUCTS, CONCENTRATES, AND EXTRACTS (1) To produce marijuana-infused products or engage in chemical manufacturing, a licensee must:

(a) ensure the registered premises and equipment are maintained in a clean and sanitary condition for product preparation purposes;

(b) use equipment, counters, and surfaces for processing that are food grade, do not react adversely with any solvent being used, reduce the potential for development of microbials, molds and fungi, and can be easily cleaned;

(c) maintain detailed instructions for making each infused product, concentrate, or extract;

(d) conduct necessary safety checks prior to commencing processing; and

(e) create written detailed operating procedures for:

(i) cleaning all equipment, counters, and surfaces thoroughly;

(ii) proper handling and storage of any solvent, gas, or other chemical used in processing or on the registered premises;

(iii) proper disposal of any waste produced during processing;

(iv) training licensee employees on how to use the system and handle and store the solvents and gases safely; and

(v) any other written procedures required by the department.

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

(a) only use hydrocarbon-based solvents that are at least 99 percent purity;

(b) only use nonhydrocarbon-based solvents that are food grade;

(c) work in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present;

(d) use only potable water and ice made from potable water in processing;

(e) process in a fully enclosed room;

(f) use a professional grade closed loop extraction system designed to recover the solvents;

(g) have equipment and facilities used in processing approved for use by the local fire code official;

(h) have an emergency eye-wash station in any room in which chemical manufacturing is occurring;

(i) have all applicable material safety data sheets readily available; and

(j) establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergencies at all registered premises.

(3) A licensee with a chemical manufacturing endorsement may use:

(a) a mechanical extraction process;

- (b) a chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or
- (c) a chemical extraction process using the solvent carbon dioxide, provided that the process:
 - (i) does not involve the use of heat over 180 degrees fahrenheit; and
 - (ii) uses a professional grade closed-loop carbon dioxide gas extraction system where every vessel is rated to a minimum of six hundred pounds per square inch.
- (4) A licensee with a chemical manufacturing endorsement may not use:
 - (a) class I solvents;
 - (b) pressurized canned flammable fuel intended for use in camp stoves, handheld torch devices, refillable cigarette lighters, and similar products; or
 - (c) denatured alcohol.
- (5) A licensee may not treat or otherwise alter a marijuana item with any noncannabinoid additive that would increase potency, toxicity, or addictive potential that would create an unsafe combination with other psychoactive substances.

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 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) licensee business or trade name and licensee registration number;
 - (b) date of harvest of marijuana or date the marijuana item was manufactured;
 - (c) name of strain or marijuana item (common or usual name);
 - (d) net weight or volume in U.S. customary and metric units;
 - (e) concentration by weight or volume of THC, THCA, CBD, and CBDA;
 - (f) amount suggested for use by the registered cardholder at any one time;
- and
- (g) unique identification number.

(2) Labels must include a consumer warning that states:

- (a) "For use by Montana Medical Marijuana Program registered cardholders only. Keep out of reach of children.";
- (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."; and
- (c) "This product is not approved by the U.S. Food and Drug Administration (FDA) to treat, cure, or prevent any disease."

(3) If the marijuana item has passed required testing, the licensee must include on the label: "This Product Has Been Tested and Meets the Quality Assurance Requirements of the State of Montana."

(4) Licensees with ten or fewer registered cardholders who are not required to submit marijuana items for testing and have not submitted marijuana items for testing must include on the label: "This Product Has Not Been Tested for compliance with Quality Assurance Requirements of the State of Montana."

(5) Additional labeling requirements for marijuana topicals, ointments, suppositories, and other marijuana products not intended to be administered orally must include:

- (a) "DO NOT EAT" in bold capital letters; and
- (b) a list of ingredients in descending order or predominance by weight or volume used to process the product.

(6) Additional labeling requirements for edible marijuana products and tinctures must include:

- (a) "BE CAUTIOUS" in bold capital letters, followed by "This product can take up to two hours or more to take effect";
- (b) if the marijuana item is perishable, a statement that the marijuana item must be refrigerated or kept frozen;
- (c) list of potential major food allergens;
- (d) a "contains" statement to summarize the major food allergen information at the end of or immediately adjacent to the ingredient list; or
- (e) a statement of the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen.

(7) Additional labeling requirements for marijuana concentrates and extracts must include:

- (a) "DO NOT EAT" in bold capital letters;
 - (b) extraction method and solvent.
- (8) Labels required by these rules must:
- (a) be placed on the container and on any packaging, that is used to display marijuana items for sale or transfer to a registered cardholder;
 - (b) be in no smaller than eight point Times New Roman, Helvetica, or Arial font;
 - (c) be in English; and
 - (d) be unobstructed and conspicuous.
- (9) Marijuana items may have one or more labels affixed to the container or packaging if necessary.

(10) Licensees may use a peel-back or accordion label with the required information if the peel-back or accordion label can be easily identified by a registered cardholder as containing important information.

(11) A label may not:

- (a) contain any untruthful or misleading statements; or
- (b) be attractive to minors.

(12) If a marijuana item is placed in a package that is being reused, the old label or labels must be removed and it must have a new label or labels.

(13) Exit packaging must contain a label that reads: "Keep out of the reach of children."

AUTH: 50-46-344, MCA

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

NEW RULE VIII PACKAGING FOR SALE TO CONSUMER (1) Containers or packaging for usable marijuana items must protect the product from contamination and must not impart any toxic or deleterious substance to the product.

(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; and

(d) labeled in accordance with [NEW RULE VII].

AUTH: 50-46-344, MCA

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

NEW RULE IX QUALITY ASSURANCE TESTING SAMPLE REQUIREMENTS (1) A licensee must separate each harvest lot of usable marijuana into no larger than five-pound test batches.

(2) A licensee must separate each process lot of a marijuana-infused product into no larger than 5,000 unit-of-sale test batches.

(3) A process lot is considered a test batch for marijuana concentrates and extracts.

(4) Usable marijuana consisting of dried leaves and flowers may only be sampled after it is cured.

(5) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests.

(6) A licensee must provide a laboratory the following documentation at the time of testing:

(a) the unique identification number;

(b) licensee business or trade name and licensee registration number;

(c) the date the sample was collected;

(d) the weight of the sample; and

(e) whether the tests being requested are:

(i) compliance tests;

(ii) quality control or research and development tests;

(iii) being re-sampled because of a failed test; or

(iv) being retested after undergoing remediation or sterilization.

(7) Following samples being taken from a harvest or process lot, a licensee must label each test batch with:

(a) the name and accreditation number of the laboratory responsible for the testing;

(b) the sample unique identification numbers supplied by the laboratory personnel;

(c) the date the samples were taken; and

(d) in bold capital letters, no smaller than 12-point font, "PRODUCT NOT TESTED."

(8) The licensee must store and secure the test batch in a manner that prevents the product from being tampered with or sold or transferred to a registered cardholder prior to test results being reported.

(9) If the marijuana item is being resampled after a failed test the licensee must provide the secondary laboratory with documentation of the failed test.

(10) A licensee may only order tests for marijuana items the licensee has produced or processed.

AUTH: 50-46-344, MCA

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

NEW RULE X QUALITY ASSURANCE TESTING REQUIREMENTS

(1) 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) cannabinoid profile;
- (b) moisture analysis;
- (c) foreign matter screening;
- (d) microbiological screening;
- (e) heavy metals screening; and
- (f) pesticides screening.

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

- (a) cannabinoid profile;
- (b) microbiological screening;
- (c) heavy metals screening;
- (d) residual solvents screening; and
- (e) pesticides screening.

(4) Marijuana-infused products must be tested for the following:

- (a) cannabinoid profile.

(5) The cannabinoid profile for each sample must include:

- (a) THCA;
- (b) THC;
- (c) Total THC;
- (d) CBDA;
- (e) CBD; and
- (f) Total CBD.

(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) moisture content more than fifteen 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 percent of stems 3mm or more in diameter; and
- (b) five percent of seeds or other foreign matter.

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

- (a) Salmonella: 10 CFU/g;
- (b) E. Coli: 10 CFU/g;
- (c) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg; and
- (d) Ochratoxin A: 20 µg/kg of substance.

(9) A sample and related lot or test batch fail quality assurance testing for residual solvents if the results exceed the limits provided in the table below.

Residual Solvents	
Solvent*	ppm
Acetone	5,000
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene**	2,170

* And isomers thereof.

** Usually 60% m-xylene, 14% p-xylene, 9% o-xylene with 17% ethyl benzene.

(10) 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	1 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

(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	30560-19-1	0.4	2
Acequinocyl	57960-19-7	2	10
Acetamiprid	135410-20-7	0.2	1
Aldicarb	116-06-3	0.4	2
Azoxystrobin	131860-33-8	0.2	1
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	1
Carbofuran	1563-66-2	0.2	1
Chlorantraniliprole	500008-45-7	0.2	1
Chlorfenapyr	122453-73-0	1	5
Chlorpyrifos	2921-88-2	0.2	1
Clofentezine	74115-24-5	0.2	1
Cyfluthrin	68359-37-5	1	5
Cypermethrin	52315-07-8	1	5
Daminozide	1596-84-5	1	5
DDVP (Dichlorvos)	62-73-7	0.1	0.5
Diazinon	333-41-5	0.2	1
Dimethoate	60-51-5	0.2	1
Ethoprophos	13194-48-4	0.2	1
Etofenprox	80844-07-1	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	1	5
Fludioxonil	131341-86-1	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 XI FAILED TEST SAMPLES (1) If a sample fails any initial test, the laboratory that did the testing must reanalyze the sample.

(2) A licensee must request a reanalysis within seven calendar days of receiving notice from the laboratory of any failed testing.

(3) The reanalysis must be completed by the laboratory within 30 days of receiving the request from the licensee.

(4) If the sample passes reanalysis, a second laboratory must sample the test batch and confirm the results for the test batch to pass testing.

(5) The licensee is responsible for the costs of reanalysis.

(6) A licensee is not permitted to sell or transfer to a registered cardholder, marijuana items that have failed a test.

(7) Failed harvests, lots, or test batches may be remediated so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product.

(8) Remediation methods used on the marijuana item must be disclosed to the department.

(9) No remediated harvests, lots, or test batches may be sold until the completion and successful passage of quality assurance testing as required in these rules and Montana statute.

(10) If a sample fails and cannot be remediated or sterilized the test batch must be destroyed.

(11) A licensee must document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.

AUTH: 50-46-344, MCA

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

NEW RULE XII MARIJUANA TESTING LABORATORY LICENSEE REQUIREMENTS (1) A licensed marijuana testing laboratory may:

(a) obtain samples of marijuana items from licensees for testing as provided in these rules;

(b) transport and dispose of samples as provided in these rules; and

(c) perform testing on marijuana items in a manner consistent with the laboratory's accreditation.

(2) A licensed laboratory may return a marijuana item obtained for purposes of testing to the licensee. The return of such marijuana items must be documented.

(3) A laboratory must document the following:

(a) receipt of samples for testing;

(b) size of the sample;

(c) licensee from whom the sample was obtained;

(d) date the sample was collected;

(e) tests performed on samples;

(f) date testing was performed;

(g) results of all testing performed; and

(h) disposition of any testing sample material.

(4) A licensee must clearly identify all limited access areas at the premises.

(5) All licensee employees must wear a 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 the date they visited.

(7) Visitors must be accompanied by a licensee or licensee employee at all times.

(8) A licensee is responsible for the security of all marijuana items on the premises, in transit, and under the supervision of any licensee or licensee employee.

(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) Commercial grade, nonresidential door locks must be installed on every external door, and gate if applicable, of premises.

(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;

(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) A licensee must establish written standard operating procedures for each test being conducted and maintain them on the premises.

(13) A licensee must maintain the following records for at least three years. Records may be kept in either paper or electronic form on the premises:

(a) financial records that clearly reflect all financial transactions;

(b) testing documentation; and

(c) all licensee employee training and payroll records.

(14) A licensee must establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergency at all premises.

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 MARIJUANA TESTING LABORATORIES

ACCREDITATION (1) A laboratory licensee must be ISO 17025 accredited.

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

(a) may submit an application for licensure pending the accreditation approval; and

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

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

(4) If a laboratory's 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 INVENTORY TRACKING SYSTEM USER

REQUIREMENTS (1) A licensee must have an 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) Additional licensees or licensee employees may be authorized to obtain inventory tracking system user accounts.

(3) To obtain and maintain an inventory tracking system user account, a licensee or licensee employee must successfully complete all required department inventory tracking system training.

(4) An individual entering data into the inventory tracking system may only use that individual's inventory tracking system account.

(5) A licensee must ensure:

(a) all inventory tracking system users are up to date on inventory tracking system user training requirements; and

(b) any data that is entered into the inventory tracking system in error is corrected.

(6) A licensee and any designated inventory tracking system user must enter data into the inventory tracking system that accounts for all inventory tracking activities.

(7) A licensee is accountable for all actions inventory tracking system users take while logged into the inventory tracking system.

(8) A licensee is responsible for the accuracy of all information entered into the inventory tracking system.

(9) Nothing in this rule prohibits a licensee from using secondary separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems.

(10) If a licensee uses a separate software application that links to the inventory tracking system it must get approval from the inventory tracking system vendor contracting with the department and the software application must:

(a) accurately transfer all relevant inventory tracking system data to and from the inventory tracking system; and

(b) preserve original inventory tracking system data when transferred to and from a secondary application.

(11) If a licensee loses access to the inventory tracking system, the licensee must keep and maintain comprehensive records detailing all tracking inventory activities that were conducted during the loss of access.

(12) Once access is restored, all inventory tracking activities that occurred during the loss of access must be entered into the inventory tracking system.

(13) A licensee must document when access to the inventory tracking system was lost and when it was restored.

(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) All compliance notifications from the inventory tracking system must be resolved in a timely fashion.

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 XV INVENTORY TRACKING AND RECONCILIATION (1) A

licensee must use the department's selected inventory tracking system as the primary inventory and record keeping system.

(2) Each individual marijuana plant that reaches a height of twelve inches must be issued a unique identification number in the inventory tracking system, which follows the plant through all phases of production and final sale to a registered cardholder.

(3) All marijuana items, test batches, harvest lots, and process lots must be issued a unique identification number in the inventory tracking system.

(4) Unique identification numbers cannot be reused.

(5) Each marijuana plant, marijuana item, test batch, harvest lot, and process lot that has been issued a unique identification number must have a physical tag placed on it with the unique identification number.

(6) The tag must be legible and placed in a position that can be clearly read and must be kept free from dirt and debris.

(7) Licensees must use unique identification tags provided by the department.

(8) All on-premises and in-transit marijuana item inventories must be reconciled in the inventory tracking system at the close of business each day.

(9) For each marijuana sale or transfer to a registered cardholder, the following must be recorded in the inventory tracking system at the close of business each day:

(a) the amount;

(b) the price before tax; and

(c) the date of the sale or transfer to a registered cardholder.

(10) Licensees must record in the inventory tracking system:

(a) wet weight of all harvested marijuana plants immediately after harvest;

(b) information for marijuana items by unit count;

(c) weight per unit of a product;

(d) weight and disposal of post-harvest waste materials;

(e) theft or loss of marijuana items; and

(f) other information as may be required by the department.

(11) These requirements do not apply to marijuana items held by a laboratory licensee that are undergoing analytical testing, so long as the marijuana items do not leave the laboratory's licensed premises and are reconciled on the same day that the quality assurance testing concludes.

(12) All samples taken for quality assurance testing must be recorded in the inventory tracking system.

(13) Licensed testing laboratories must record all testing results in the inventory tracking system.

(14) All transport manifests must be generated by the inventory tracking system and contain all the information required by these rules.

(15) A receiving location must document in the inventory tracking system any marijuana items received, and any differences between the quantity specified in the transport manifest and the quantities received.

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 TRANSPORTATION AND DELIVERY OF MARIJUANA

ITEMS (1) Marijuana items may only be transported between registered premises or licensed testing laboratories by a licensee or licensee employee.

(2) A printed transport manifest must accompany every transport of marijuana items. The manifest must contain the following information:

- (a) registered premises address and license number of departure location;
- (b) address and license number or cardholder number of receiving location;
- (c) product name, quantities (by weight or unit), and unique identification numbers of each marijuana item to be transported;
- (d) date and time of departure;
- (e) date and time of arrival;
- (f) delivery vehicle make, model, and license plate number; and
- (g) name and signature of each licensee or licensee employee accompanying the transport.

(3) The transport manifest may not be voided or changed after departing from the originating registered premises.

(4) A copy of the transport manifest must be given to each location receiving the inventory described in the transport manifest.

(5) A registered premises is prohibited from receiving any marijuana items from transit without a valid transport manifest.

(6) The receiving location must ensure that the marijuana items received are as described in the transport manifest and must record receipt of the inventory.

(7) The receiving location must document any differences between the quantity specified in the transport manifest and the quantities received.

- (8) Any vehicle transporting marijuana items must be capable of:
- (a) keeping marijuana items in transit shielded from public view;
 - (b) securing (locking) the marijuana items during transportation; and
 - (c) being temperature controlled if perishable marijuana items are being transported.

(9) A licensee must contact the department within 24 hours if a vehicle transporting marijuana items is involved in an accident that involves product loss.

(10) Copies of the transport manifest and delivery receipts must be presented to law enforcement officers or authorized department employees if requested.

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 WASTE MANAGEMENT (1) A licensee must store, manage, and dispose of solid and liquid waste generated during marijuana production and processing in accordance with applicable state and local laws and regulations.

(2) A licensee must store marijuana waste in a secured waste receptacle in the possession of and under the control of the licensee.

(3) Waste that must be rendered unusable prior to disposal includes:

- (a) marijuana plant waste, including roots, stalks, leaves, and stems that have not been processed with solvent;
 - (b) waste solvents used in the marijuana process;
 - (c) spent solvents, laboratory waste, and excess marijuana from any quality assurance testing; and
 - (d) marijuana items that ultimately fail to meet testing requirements.
- (4) A licensee must maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana to include:
- (a) what was disposed;
 - (b) quantity by weight or volume;
 - (c) date disposed;
 - (d) disposal method;
 - (e) reason for the disposal;
 - (f) identity of who disposed the waste; and
 - (g) record of the destination of marijuana waste rendered unusable.
- (5) A licensee must provide a minimum of 72 hours' notice in the inventory tracking system prior to rendering the marijuana item unusable and disposing of it.

AUTH: 50-46-344, MCA

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

NEW RULE XVIII MARIJUANA ITEM RECALLS (1) The department may require a licensee to recall any marijuana item that the licensee has sold or transferred to a registered cardholder that poses a risk to public health and safety.

(2) A recall may be based on evidence that a usable marijuana item is contaminated or otherwise unfit for human use, consumption, or application.

(3) If the department determines that a recall is required, the licensee must notify the registered cardholder or cardholders to whom the marijuana item was sold and destroy the recalled product.

AUTH: 50-46-344, MCA

IMP: 50-46-326, MCA

NEW RULE XIX REPORTING REQUIREMENTS (1) A registered cardholder must notify the department within ten calendar days of any changes in the following:

- (a) cardholder's name or address;
- (b) referral physician;
- (c) provider or marijuana-infused products provider; or
- (d) change in the status of the cardholder's debilitating medical condition.

(2) A registered cardholder that is their own provider, must notify the department ten calendar days prior to the change in location of plants or seedlings.

(3) A registered cardholder must report to the department within ten calendar days any lost or stolen registry identification card.

(4) A licensee must notify the department within 30 calendar days of any changes in the following:

- (a) anyone identified as an applicant;
 - (b) temporary closure of longer than 30 days; and
 - (c) permanent closure of the business.
- (5) A licensee who wishes to change the location of a registered premises must submit a completed application for the new premises including all required forms, documents, and fees.
- (6) A licensee who intends to make any material or substantial changes to the registered premises must submit the changes to the department for approval prior to making any such changes. Material or substantial changes include:
- (a) any increase or decrease in the total physical size or capacity of the registered premises;
 - (b) alterations to public ingress or egress of limited access areas;
 - (c) any changes to the security plan.
- (7) A licensee must notify the department as soon as reasonably practical but in no case more than 24 hours following the theft of marijuana items or money from the registered premises.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-307, 50-46-308, 50-46-311, MCA

NEW RULE XX INSPECTIONS (1) The department may conduct inspections to determine compliance with these rules and Montana statutes. To include:

- (a) an initial application inspection;
 - (b) annual renewal inspections;
 - (c) unannounced inspections; and
 - (d) complaint inspections.
- (2) A licensee or licensee employee must cooperate with the department during an inspection.
- (3) A licensee or licensee employee may not:
- (a) refuse to admit a department regulatory surveyor from entering a registered premises to conduct an inspection; or
 - (b) ask the regulatory surveyor to leave until the surveyor has had an opportunity to fully conduct an inspection.
- (4) If a licensee or licensee employee fails to permit the department to conduct an inspection, the department may deny, suspend, or revoke their license or endorsement.
- (5) If during an inspection the department determines the applicant is not in compliance with applicable licensing requirements or Montana statute, the department will notify the applicant of the specific deficiencies or errors.
- (6) The department will not issue a license or renew a license until all required or corrected information has been received.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-308, 50-46-311, 50-46-312, 50-46-319, 50-46-328, 50-46-329, MCA

4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.107.110 DEFINITIONS ~~For purposes of the Montana marijuana registry:~~

(1) remains the same.

(2) "Authorized employee" means:

(a) and (b) remain the same.

(c) an employee of a state or local government agency, including a state or local law enforcement agency, who has received ~~written~~ authorization to obtain marijuana registry information. ~~Written authorization, as applicable, must be provided to the department from a state agency director or director's designee, county sheriff, police chief, county attorney, or city attorney.~~

(3) "CBD" means cannabidiol.

(4) "CBDA" means cannabidiolic acid.

~~(3)~~ (5) "Cultivate" means to grow, propagate, clone, or harvest marijuana for use by registered cardholders.

(6) "Department" means the Department of Public Health and Human Services.

(7) "Exit package" means a sealed container or package provided at the retail point of sale, in which any marijuana item already within a container is placed.

~~(4)~~ (8) "Fee" means the mandatory fees ~~necessary to process a marijuana registry card application~~ required by the department.

~~(5)~~ (9) "Fingerprint card" means the department's an FD-258 fingerprint card utilized to facilitate a Federal Bureau of Investigation (FBI) fingerprint and background check ~~for provider or MIPP applicants.~~

(10) "Food-Grade" means the processing and packaging has been done with clean equipment and can be safely eaten.

(11) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 48 hour period at the same location, and cured under uniform conditions.

(12) "ISO" means International Organization for Standardization.

~~(6)~~ (13) "Landlord Permission Form" means a completed, signed, and notarized form which gives a ~~registrant~~ registered cardholder, applicant, or licensee who is renting or leasing the property where marijuana will be cultivated and manufactured for medical purposes, permission to do so, by the property owner. The form must be provided by the department.

(14) "Licensee" means any person licensed by the department.

(15) "Limited access area" means a building, room, or other contiguous area upon the registered premises where marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under the control of the licensee.

~~(7)~~ (16) "Manufacture" means the act of preparing and processing usable marijuana into a marijuana-infused product. A marijuana-infused product must be labeled as to indicate that it contains marijuana.

(17) "Marijuana items" means:

(a) marijuana;

(b) usable marijuana;

(c) dried leaves and flowers of the marijuana plant;

(d) marijuana derivatives, concentrates, extracts, resins, infused products, edible products, ointments, tinctures, suppositories, topicals; and

(e) other marijuana-related products.

~~(8)~~ (18) "Physician statement" means a written statement by a Montana licensed physician on ~~one of three~~ department forms certifying the registered cardholder applicant's debilitating condition. Physician statement forms include:

(a) Physician Statement for Debilitating Condition; or

~~(b) Physician Statement for Chronic Pain Diagnosis; or~~

~~(c)~~ (b) Physician Statement for Minors.

(19) "Process lot" means:

(a) any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures, and test batches from the same or different harvest lots; or

(b) any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures, and test batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.

(9) remains the same, but is renumbered (20).

(21) "Registered premises" means the premises specified in an application for a license that is owned or in possession of the licensee and within which the licensee is authorized to cultivate, manufacture, dispense, store, transport, or test medical marijuana.

~~(10) "Registrant" means any provider, MIPP, or registered cardholder who has been approved for, and entered into, the department registry.~~

~~(11)~~ (22) "Registry" means the department's confidential marijuana record identifying marijuana registered cardholders, providers, and MIPPs.

~~(12) "Residential health care facility" means an adult day care center, an adult foster care home, an assisted living facility, or a retirement home as defined in 50-5-101, MCA.~~

(23) "Test Batch" means a portion of a harvest or process lot that has been submitted for quality assurance testing.

(24) "THC" means tetrahydrocannabinol.

(25) "THCA" means tetrahydrocannabinolic acid.

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

37.107.111 REGISTERED CARDHOLDER APPLICATION PROCESS

~~(1) All applicants~~ An applicant must have a Montana mailing address and submit an application packet on forms provided by the department for consideration to be placed in the registry be a resident of the State of Montana under 1-1-215, MCA.

~~(2) Application forms are available from and must be submitted to the Department of Public Health and Human Services, Licensure Bureau, 2401 Colonial Drive, P.O. Box 202953, Helena, MT 59620-2953. Application forms are also available on the department's web site at www.dphhs.mt.gov/marijuana.~~

~~(3) Registered cardholder application materials that must be provided include:~~

~~(a) State of Montana Marijuana Registered Cardholder Application Form.~~

~~The information on this form includes:~~

~~(i) the applicant's name, address, date of birth, and social security number;~~

~~(ii) verification that the applicant:~~

~~(A) will cultivate and manufacture marijuana for the applicant's own use; or~~

~~(B) will obtain marijuana from a provider or marijuana-infused products provider.~~

~~(iii) verification that the applicant agrees to not divert to any other person the marijuana that the applicant cultivates, manufactures, or obtains for the applicant's debilitating medical condition; and~~

~~(iv) verification that the applicant is not in the custody of, or under the supervision of, the Montana Department of Corrections (DOC) or a youth court.~~

~~(b) proof of residency;~~

~~(c) signed, applicable Physician Statement attesting to the applicant's diagnosis of a debilitating medical condition as defined in 50-46-302, MCA, diagnosis of chronic pain, or certification for use by a minor. The Physician Statement includes:~~

~~(i) physician's name, address, and telephone number; and~~

~~(ii) physician's Montana medical license number.~~

~~(d) applicable fees as outlined in ARM 37.107.117; and~~

~~(e) landlord permission form, if applicable.~~

~~(4) The department will verify with the Montana Board of Medical Examiners that the attending physician, and, if applicable, the referral physician, are licensed to practice medicine in Montana and the license is in good standing.~~

~~(5) The department must either approve or deny a registered cardholder application within 30 business days of receiving completed application materials. If approved, the department must issue a registry identification card within five business days of approving the application.~~

~~(6) Applicants who designate, on the application form, a provider or a MIPP who is not already registered with the department, will be issued a registry identification card listing no provider or MIPP.~~

~~(a) Named providers or MIPPs who are not already registered with the department will be required to submit application materials and be approved for the registry by the department, before they can be a provider or MIPP.~~

~~(b) Upon approval by the department, the registered cardholder will be issued a new card with the name of the registered provider or MIPP.~~

~~(7) The registry identification card expires one year from the date of issuance except when:~~

~~(a) the physician statement provides a written certification for a shorter period of time; or~~

~~(b) a registered cardholder changes provider or MIPP. When a change request form is received, processed, and approved by the department the registered cardholder's current card becomes void. The new card is not valid until it is received by the registered cardholder.~~

~~(8) Incomplete application packets will be handled pursuant to ARM 37.107.121.~~

~~(9) If the registered cardholder application is denied, the department will send the applicant notice of and reasons for the denial. Rejection of the application is considered a final department action, subject to judicial review.~~

~~(2) All applications must be completed on forms provided by the department.~~

~~(3) A complete application must include the required fee, statements, and forms required in the application packet to be accepted and processed by the department.~~

~~(4) The registry identification card expires one year from the date of issuance with the exception of the following:~~

~~(a) the physician statement provides a written certification for a shorter period of time; or~~

~~(b) a registered cardholder changes provider or marijuana-infused products provider.~~

~~(5) Renewal applications must be submitted within 30 calendar days prior to the expiration date of the license.~~

~~(6) The department will approve or deny an application within 30 calendar days of receiving a complete application.~~

~~(7) A registered cardholder may not purchase, grow, or possess marijuana items prior to the effective date of the registration card.~~

~~(8) Any denial under this part is subject to judicial review.~~

~~(9) A custodial parent or legal guardian may submit an application for a minor under 50-46-307, MCA.~~

~~(10) An applicant must designate either a licensed provider or licensed marijuana-infused products provider, unless the registered cardholder intends to cultivate or manufacture marijuana for their own use under 50-46-303, MCA. If the registered cardholder intends to cultivate or manufacture marijuana for their own use, a landlord permission form must also be submitted if applicable.~~

AUTH: 50-46-344, MCA

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

37.107.115 PROVIDER OR MIPP LICENSE AND ENDORSEMENT

APPLICATION PROCESS (1) ~~Provider/MIPP applicants must be: An applicant must be a resident of the State of Montana under 1-1-215, MCA.~~

~~(a) a Montana resident; and~~

~~(b) named by a registered cardholder on the cardholder's application or change request form.~~

~~(2) Provider application materials are available from the Department of Public Health and Human Services, Licensure Bureau, 2401 Colonial Drive, P.O. Box 202953, Helena, MT 59620-2953. Application forms are available on the department's web site at www.dphhs.mt.gov/marijuana. Completed provider/MIPP application materials must include:~~

~~(a) Provider/MIPP Application form that includes:~~

~~(i) the applicant's name, address, date of birth, and social security number;~~

~~and~~

- ~~(ii) verification that the applicant:~~
 - ~~(A) is not in the custody of, or under the supervision of, the DOC or a youth court;~~
 - ~~(B) does not have a felony conviction or a conviction for any drug offense;~~
 - ~~(C) has not been convicted of a violation under 50-46-331, MCA;~~
 - ~~(D) has not failed to pay any taxes, interest, penalties, or judgments due to a government agency;~~
 - ~~(E) has not defaulted on a government-issued student loan;~~
 - ~~(F) has not failed to pay child support; and~~
 - ~~(G) has not failed to remedy an outstanding delinquency for child support or for taxes or judgments owed to a government agency;~~
- ~~(b) applicable fee as specified in ARM 37.107.117;~~
- ~~(c) legible copy of the individual's Montana driver's license or other Montana state-issued identification card; and~~
- ~~(d) fingerprint cards as required by ARM 37.107.119.~~
- ~~(3) The department must either approve or deny a provider or MIPP application within 30 business days of receipt of a completed application. If approved, the department must issue a registry identification card to the provider or MIPP applicant within five business days.~~
- ~~(4) Providers/MIPPs must reapply annually. Providers/MIPPs do not need to reapply every time they are named by a registered cardholder, unless it has been one year since their last application was approved.~~
- ~~(5) Provider/MIPP registration will be revoked if the provider/MIPP is no longer named by a registered cardholder.~~
- ~~(6) If a former provider/MIPP, whose registration has been revoked or has expired, is named by a registered cardholder on an application or change request form, the former provider must reapply for the program.~~
 - ~~(a) A former provider/MIPP, who is reapplying for the registry, does not require a fingerprint background check unless it has been 12 months or more from the date their fingerprints were received by the department from the Montana Department of Justice (DOJ).~~
 - ~~(b) When the former provider/MIPP is approved by the department, the \$50 provider/ MIPP application fee will be due when fingerprinting is again required pursuant to ARM 37.107.119.~~
- ~~(7) Incomplete application packets will be handled pursuant to ARM 37.107.121.~~
- ~~(8) If the provider/MIPP application is denied, the department will send the applicant notice of and the reasons for denial.~~
- ~~(9) Rejection of any application is considered a final department action, subject to judicial review.~~
 - (2) All applications must be completed on forms provided by the department.
 - (3) A complete application must include the required fee, statements, forms, diagrams, operation plans, and other applicable documents required in the application packet to be accepted and processed by the department.
 - (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) all directors; and
- (c) principal officers of corporate applicants.
- (5) The license will expire one year from the date of issuance.
- (6) Renewal applications must be submitted at least 30 calendar days prior to the expiration date of the license.
- (7) The department will approve or deny an application within 30 calendar days of receiving a complete application.
- (8) Prior to approving an application, the department may contact any applicant or individual listed on the application and request additional supporting documentation or information.
- (9) Prior to issuing a license or endorsement, the department will inspect the proposed premises to determine if the applicant complies with these rules and Montana statute.
- (10) If a licensee fails to submit a renewal application prior to the license or endorsement expiration date, the licensee may not continue to operate.
- (11) If a renewal application is received within 30 days of expiration, the department may process the application.
- (12) The department will not consider renewal applications received more than 30 days after the license or endorsement expiration date.
- (13) An applicant or licensee may request a chemical manufacturing endorsement or dispensary license upon submission of an initial application or at any time following licensure.
- (14) Chemical manufacturing endorsements and dispensary licenses issued under this rule will expire the same date of the provider license or marijuana-infused product provider license.
- (15) A licensee:
 - (a) may not operate until on or after the effective date of the license; and
 - (b) must display proof of licensure in a prominent place on the registered premises.
- (16) A license or endorsement may not be sold or transferred.
- (17) Any denial under this part is subject to judicial review.

AUTH: 50-46-344, MCA

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

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

- (a) registered cardholder application fee of ~~\$5~~ \$30;
- (b) provider or marijuana-infused product provider with ten or fewer registered cardholders, an application fee of ~~\$50~~ \$1,000;
- (c) MIPP application fee of ~~\$50~~ provider or marijuana-infused product provider with more than ten registered cardholders, an application fee of \$5000;
- (d) a combined provider and MIPP marijuana-infused product provider with ten or fewer registered cardholders, an application fee of ~~\$50~~; and ~~\$1,000~~;

(e) annual registered cardholder renewal fee of \$5 a combined provider and marijuana-infused product provider with more than 10 registered cardholders, an application fee of \$5000;

(f) dispensary license application fee of \$500;

(g) chemical manufacturing endorsement application fee of \$500;

(h) testing laboratory application fee of \$2000;

(i) marijuana employee permit fee of \$50 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.

(2) All fees must be submitted with the application and must be paid by check or money order made payable to the Department of Public Health and Human Services. Cash is not accepted.

(3) Fees are nonrefundable regardless of final application status.

~~(4) Renewal applications received by the department after the expiration date will be treated as new applications.~~

AUTH: 50-46-344, MCA

IMP: 50-46-344, MCA

37.107.119 PROVIDER AND MIPP 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;

(b) employees defined in 50-46-302, MCA; and

(c) a parent or guardian of a minor serving as the minor's provider.

~~(4) (2) Two fingerprint cards must be completed and acceptable fingerprint cards must be submitted with provider/MIPP application materials by a trained individual within a certified fingerprinting agency and submitted to the department. The fingerprint cards provided by the department are the only fingerprint cards to be accepted for this purpose. Photocopied duplicates are not valid.~~

~~(2) The fingerprint card must be processed under these conditions:~~

~~(a) fingerprints must be rolled onto each of the two provided fingerprint cards by a trained individual within a Montana law enforcement agency; and~~

~~(b) the individual rolling the prints must maintain control and possession of the fingerprint cards once the prints are rolled onto the cards and must place the cards into an envelope, seal it, and mail it to the department:~~

~~(i) The individual rolling the prints may also place the applicant's application and applicable fee into the envelope as long as the individual rolling the prints maintains control and possession of the fingerprint cards as required by this rule.~~

~~(3) Upon completion of the fingerprint background check, the DOJ will return both fingerprint cards to the department. Upon receipt of the cards, the department will destroy the returned fingerprint cards.~~

~~(4) If an adequate set of readable fingerprints cannot be obtained, the DOJ will notify the department that a federal name-based background check has been submitted for the named individual.~~

~~(a) (3) If an adequate set of fingerprints cannot be obtained, a Federal name-based background checks can be conducted but may take up to 90 days to complete.~~

~~(5) Fingerprint cards are considered complete when they are returned to the department by the DOJ. The 30 business day application approval time required by the department will begin on the day the fingerprint cards are returned.~~

~~(6) The fingerprint background checks are valid for a 12-month period. Thirty calendar days prior to the expiration date of the background check, new prints must be obtained following the same procedures outlined in this rule and returned to the department by the DOJ.~~

(4) Fingerprint background checks are required with the initial application and annual renewal applications.

(5) Results of background checks must be received prior to:

(a) approval of any application; and

(b) issuance of a marijuana employee permit.

~~(7) (6) If the law enforcement certified fingerprinting agency charges a fee for fingerprinting, the applicant is responsible for the fee.~~

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-307, 50-46-308, 50-46-311, 50-46-344, MCA

37.107.127 INVALIDATION OR REVOCATION DENIAL OF REGISTRY IDENTIFICATION CARDS APPLICATION OR REVOCATION OF REGISTRY IDENTIFICATION CARD

~~(1) A registry card for a registered cardholder can be revoked for the following reasons:~~

~~(a) the registered cardholder no longer has a debilitating medical condition;~~

~~(b) the written recommendation has been rescinded by the physician;~~

~~(c) the registrant is now in the custody of, or under the supervision of, the DOC or a youth court;~~

~~(d) the registered cardholder fails to report to the department within ten business days a change:~~

~~(i) in name;~~

~~(ii) in street, mailing, or physical address;~~

~~(iii) in physician;~~

~~(iv) in provider/MIPP; or~~

~~(v) concerning the debilitating medical condition.~~

~~(e) a landlord revokes their permission in writing and a change request form, with a new physical address, is not received within ten business days of the receipt of the revocation;~~

~~(f) a registered cardholder is found to be in violation of 50-46-330, MCA or 50-46-331, MCA; or~~

~~(g) mail sent to the registered cardholder by the department is returned, undeliverable by the United States Postal Service (USPS), and no change of address is submitted within twenty business days after the day the mail is returned to the department.~~

~~(2) In addition to the criteria stated in 50-46-308, MCA the department will revoke an active provider/MIPP registry identification card if the department~~

determines that the provider/MIPP has violated the provisions of the Montana Marijuana Act in the following ways:

~~(a) the provider/MIPP pleads guilty to, or is convicted of, any offense related to driving under the influence of alcohol or drugs;~~

~~(i) a registry card revocation under this circumstance must be for the period of suspension or revocation of the individual's driver's license as set forth in 61-5-208 and 61-8-410, MCA. If a provider/MIPP registry card is due to be renewed during a period of driver's license revocation, it may not be renewed by the department until the term of the driver's license revocation has elapsed.~~

~~(b) fails to report to the department a change in name or address within ten business days of the change;~~

~~(c) a provider/MIPP whose registry identification was issued under Section 35, Ch. 419, L. 2011 fails to submit fingerprints and pass a fingerprint background check by October 1, 2011;~~

~~(d) the results of a fingerprint background check conducted after issuance of the registry card show that the person is ineligible for the card pursuant to 50-46-308, MCA;~~

~~(e) the provider/MIPP is no longer named by any registered cardholder on their application or change request form; or~~

~~(f) mail sent to the provider/MIPP by the department is returned, undeliverable by the USPS, and no change of address is submitted within 20 business days after the day the mail is returned to the department.~~

~~(3) A registration card is not valid if the card has been altered or mutilated. A photocopy of the registry card is not valid.~~

~~(4) If a provider/MIPP registry card is revoked for any reason, the department will notify the provider/MIPP and the registered cardholder in writing and advise the registered cardholder that the provider/MIPP can no longer assist them.~~

(1) The department, after written notice to the applicant or registered cardholder, may deny or revoke an application or registry identification card if:

(a) the applicant did not provide the information required in the application;

(b) the department determines the information provided in the application was inaccurate, misleading or falsified;

(c) the applicant did not submit the required fee with the application;

(d) the applicant or registered cardholder does not have or no longer has a debilitating medical condition as defined in 50-46-302, MCA;

(e) the applicant is not a resident of the State of Montana;

(f) the applicant is in the custody of or under supervision of the Department of Corrections or youth court;

(g) the applicant or registered cardholder has been convicted of driving under the influence of alcohol or drugs under 50-46-320, MCA;

(h) the applicant or registered cardholder is found to be in violation of 50-46-330, MCA;

(i) the department is notified in writing by a landlord revoking permission under 50-46-307, MCA;

(j) the applicant or registered cardholder did not report changes to the department in accordance with [NEW RULE XIX];

(k) the registry identification card has been found to be altered or manipulated in any way; or

(l) any violations otherwise under Title 50, chapter 46, part 3, MCA have occurred.

(2) Any denial or revocation under this part is subject to judicial review.

AUTH: 50-46-344, MCA

IMP: Section 35, Ch. 419, L. 2011, 45-9-203, 50-46-303, 50-46-308, 50-46-320, 50-46-344, 61-11-101, MCA

37.107.128 LEGAL PROTECTIONS -- ALLOWABLE AMOUNTS (1) A registered cardholder who has named a provider may possess up to 1 ounce of useable marijuana.

~~(2) (1) A registered cardholder who has not named a provider may possess up to 4 mature plants, 12 seedlings, and 1 ounce of useable usable marijuana.~~

~~(3) A provider or marijuana-infused products provider may possess 4 mature plants, 12 seedlings, and 1 ounce of useable marijuana for each registered cardholder who has named the person as the registered cardholder's provider.~~

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-319, 50-46-344, MCA

5. The department proposes to repeal the following rules:

37.107.113 MINOR APPLICATION PROCESS is found on page 37-26713 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA

IMP: 50-46-303, 50-46-307, 50-46-344, MCA

37.107.116 CHEMICAL MANUFACTURING ENDORSEMENTS is found on page 37-26715 of the Administrative Rules of Montana.

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

37.107.121 INCOMPLETE APPLICATION, RENEWAL, OR CHANGE REQUESTS is found on page 37-26717 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA

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

37.107.123 PROPERTY RESTRICTIONS is found on page 37-26717 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA

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

37.107.125 REPLACING LOST OR STOLEN REGISTRY IDENTIFICATION CARDS is found on page 37-26718 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-344, MCA

37.107.129 NOTIFICATION TO LOCAL LAW ENFORCEMENT is found on page 37-26721 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-344, MCA

37.107.132 TESTING LABORATORIES is found on page 37-26721 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-311, 50-46-312, 50-46-328, 50-46-329, 50-46-344, MCA

37.107.133 COMPLAINT HOTLINE is found on page 37-26722 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-342, 50-46-344, MCA

37.107.135 DISCLOSURE OF CONFIDENTIAL MARIJUANA REGISTRY INFORMATION is found on page 37-26722 of the Administrative Rules of Montana.

AUTH: 50-46-344, MCA
IMP: 50-46-303, 50-46-344, MCA

6. STATEMENT OF REASONABLE NECESSITY

The 65th Montana Legislature passed Senate Bill 333 (SB333) which made significant changes to the Montana Medical Marijuana Act. SB333 requires the department to:

- a. implement an inventory tracking system;
- b. issue licenses for dispensaries and endorsements for chemical manufacturing;
- c. collect samples during the inspection of registered premises to be submitted to a testing laboratory for testing;
- d. establishes a tax on providers and a fee on dispensaries;
- e. establishes requirements for testing laboratories;

f. revises the amounts of marijuana registered cardholders and providers may possess; and

g. eliminates the requirement for a parent to serve as the provider for a minor child.

The proposed new administrative rules, ARM amendments, and repeals of rules are necessary to implement the provisions of SB333 to create a revised, more transparent, accountable, and safe medical marijuana program. The department has been conducting research, gathering input from stakeholders, and learning best practices to design a comprehensive set of rules to govern the program. Cardholders as well as those who provide and test medical marijuana and enforce the provisions need to know the requirements of the program. The proposed new and amended rules are intended to provide clear and concise guidance to applicants, licensees and endorsees, law enforcement, and departmental employees regarding the use of medical marijuana for debilitating medical conditions.

NEW RULE I

The department proposes to adopt this new rule to state that the purpose of the ARMs is to establish requirements for the Medical Marijuana Program. This is necessary to explain why the ARMs are being adopted, amended, and repealed.

NEW RULE II

The department proposes to adopt this new rule to specify the procedures for denying applications to become a provider or cardholder and revoking licenses and endorsements. This rule is necessary to put applicants and providers on notice of the reasons for which their application may be denied or their licenses and endorsements revoked and the remedy if a denial or revocation occurs.

NEW RULE III

The department proposes to adopt this rule to specify that all persons employed by licensees have an employee permit and to provide that employee permits will not be issued to a person who has been convicted of a drug offense. This rule is necessary to implement Senate Bill 333.

NEW RULE IV

The department proposes to adopt this rule that specifies how Montana residency may be verified so applicants will be aware of what verification is acceptable.

NEW RULE V

The department proposes to adopt this rule to specify the requirements for providers and marijuana-infused products providers regarding their premises, employees, procedures and other limitation on their conduct. This rule is necessary to put

licensees on notice of the rules and procedures they must follow so that they can comply with those rules and procedures.

NEW RULE VI

The department proposes to adopt this rule to specify the requirements for producing marijuana-infused products, concentrates, and extracts. This rule is necessary to put licensees on notice of requirements for the conditions of their premises, substances that may and may not be used to produce marijuana-infused products, concentrates, and extracts and procedures to be followed so they can comply with those requirements.

NEW RULE VII

The department proposes to adopt this rule to specify requirements for labeling marijuana items. This rule requires labeling that provides information about the content of items being sold to cardholders and warnings regarding limitations on use of the items and also prohibits using labels that are untruthful, misleading, or attractive to minors. This rule is necessary to implement a provision of SB 333 and to protect cardholders and others who may come in contact with the items.

NEW RULE VIII

The department proposes to adopt this rule to specify requirements for packaging usable marijuana to be sold to consumers. This rule is necessary to protect cardholders and others who may come in contact with the items, especially children.

NEW RULE IX

The department proposes to adopt this rule to specify requirements for batch samples. This rule is necessary to put licensees on notice of how marijuana and marijuana products must be batched, labeled, stored, and secured.

NEW RULE X

The department proposes to adopt this rule to specify requirements for testing marijuana and marijuana products. This rule is necessary to implement provisions of SB 333 regarding the substances for which marijuana and marijuana products will be tested and other details of the testing process and put licensees on notice of these testing requirements.

NEW RULE XI

The department proposes to adopt this rule to specify procedures to be followed when a sample fails the initial test. This rule is necessary to put licensees on notice of their right to have a sample retested, the requirements for retesting, and the consequence of failure to pass the initial or a subsequent test.

NEW RULE XII

The department proposes to adopt this rule to specify the requirements for the operation of laboratories, including required and prohibited activities, the conduct of employees, and recordkeeping. This rule is necessary to put licensees on notice of rules they must follow in the operation of their laboratories.

NEW RULE XIII

The department proposes to adopt this rule to provide that all testing laboratories must be accredited and to specify the criteria for accreditation. This rule is necessary to implement Senate Bill 333 and to put laboratories on notice of the requirement to be accredited and the process for achieving accreditation. Accreditation of laboratories is necessary to ensure the quality of marijuana items sold to cardholders.

NEW RULES XIV and XV

The department proposes to adopt these rules to provide that licensees must use the department's inventory tracking system and to specify details about the use of the tracking system. These rules are necessary to implement Senate Bill 333 and to put licensees on notices of requirements relating to use of the department's tracking system.

NEW RULE XVI

The department proposes to adopt this rule to specify requirements for the transportation of marijuana by licensees between registered premises and licensed testing laboratories. This rule is necessary to put licensees on notice of manifest requirements and other requirements concerning the delivery of marijuana.

NEW RULE XVII

The department proposes to adopt this rule to specify requirements for waste management to put licensees on notice of the requirements for storing, managing, and disposing of waste generated during marijuana production and for keeping records regarding waste materials. This is necessary so licensees can comply with those requirements.

NEW RULE XVIII

The department proposes to adopt this rule to authorize the department to require licensees to recall marijuana items that are unfit for human consumption or were not produced or processed by a licensee. This rule is necessary for the safety and protection of consumers and to make licensees aware that they must recall marijuana items under certain circumstances.

NEW RULE XIX

The department proposes to adopt this new rule to specify the duty of cardholders and licensees to report certain changes in their circumstances. This rule is necessary to implement provisions of SB 333 regarding reporting requirements and to put cardholders and licensees on notice of reporting requirements.

NEW RULE XX

The department proposes to adopt this rule to authorize the department to conduct inspections and specify when and how the department may conduct inspections. The rule also provides that providers must cooperate with the department in the inspections and specifies the consequences if a provider fails to cooperate or if the inspection shows a provider has not complied with licensing requirements. This rule is necessary to implement provisions of SB 333 regarding inspections and put providers on notice of the department's right to inspect, the providers' obligation to cooperate and the consequences of failure to cooperate or if an inspection shows a provider is deficient or otherwise out of compliance with licensing requirements.

ARM 37.107.110

ARM 37.107.110 contains definitions of terms used in the rules governing the Medical Marijuana Program. It is necessary to add a number of new definitions to clarify the meaning of terms used in the proposed new rules.

ARM 37.107.111

ARM 37.107.111 governs the application process for becoming a registered cardholder and for renewal applications, provides a remedy for denial of an application, provides an expiration date for cards, and contains requirements for registered cardholders. The department proposes to amend this rule to comply with statutes.

ARM 37.107.113

The department proposes to repeal ARM 37.107.113 specifying the process for processing a minor's application to become a registered cardholder. The repeal of this rule is necessary because the subject matter has either been moved to another rule or is otherwise covered by statute.

ARM 37.107.115

ARM 37.107.115 governs the application process to be licensed or obtain a chemical manufacturing endorsement or dispensary license. The department proposes to amend this rule to comply with statute.

ARM 37.107.116

The department proposes to repeal ARM 37.107.116 allowing for temporary chemical manufacturing endorsements as these are now addressed in other rules.

ARM 37.107.117

ARM 37.107.117 specifies the fees cardholders and providers must pay. It is necessary to amend this rule to comply with provisions of SB333 and notify cardholders and providers of what fees they will be charged. Although SB333 sets the fees for providers of marijuana and marijuana infused products at \$1,000 for providers with ten or fewer cardholders and \$5,000 for providers with more than ten cardholders, it also allows the department to revise these fees as needed to adequately fund the administration of the program and the inventory tracking program. The department has chosen to set the fees at \$1,000 and \$5,000 as established by the Legislature because the department believes these fees are adequate to fund the administration of the program and inventory tracking program at this time.

SB333 further authorizes the department to set fees for dispensaries, endorsements for chemical manufacturing and testing laboratories by rule. The department proposes to increase the fee for cardholders from \$5 to \$30 and to set the fee for dispensary licenses, chemical manufacturing endorsements and testing laboratory applications at \$500. The rule also proposes to establish an employee permit fee of \$50 per employee and a fee for amending or changing a registry identification card. The department has decided to charge these fees because the department believes they are adequate to fund the administration of the program and inventory tracking system at this time.

ARM 37.107.119

ARM 37.107.119 requires background checks for persons applying to become providers, employees, and a parent or guardian serving as a minor's provider and specifies the requirements for fingerprinting of applicants. The department proposes to amend this rule to comply with statute.

ARM 37.107.121

The department proposes to repeal ARM 37.107.121 governing incomplete applications, renewals, and change requests. The repeal of this rule is necessary because the subject matter has either been moved to another rule or is otherwise covered by statute.

ARM 37.107.123

The department proposes to repeal ARM 37.107.123 requiring cardholders and providers to notify the department whether property used to cultivate or manufacture

marijuana is owned or rented by the cardholder or provider and, if it is rented, requiring the cardholder or provider to have the landlord complete a landlord permission form. The repeal of this rule is necessary because the subject matter has either been moved to another rule or is otherwise covered by statute.

ARM 37.107.125

The department proposes to repeal ARM 37.107.125 requiring cardholders to report the loss or theft of a card and providing for issuance of a duplicate card. The repeal of this rule is necessary because the subject matter has either been moved to another rule or is otherwise covered by statute.

ARM 37.107.127

ARM 37.107.127 specifies reasons for which a cardholder's card or a provider's license may be revoked. The department proposes to amend this rule to comply with statute.

ARM 37.107.128

The department proposes to amend ARM 37.107.128 addressing the allowable amounts of marijuana to comply with statute.

ARM 37.107.129

The department proposes to repeal ARM 37.107.129 requiring the department to notify county sheriffs of providers and MIPP within their jurisdiction. The repeal of this rule is necessary because the subject matter has either been moved to another rule or is otherwise covered by statute.

ARM 37.107.132

The department proposes to repeal ARM 37.107.132 allowing for temporary testing laboratory licensing as these are now addressed in other rules.

ARM 37.107.133

The department proposes to repeal ARM 37.107.133 requiring the department to establish a hotline to receive complaints concerning the Montana Medical Marijuana Program and specifying policies regarding operation of the hotline. The repeal of this rule is necessary because the subject matter has either been moved to another ARM or is otherwise covered by statute.

ARM 37.107.135

The department proposes to repeal ARM 37.107.135 requiring the department to disclose marijuana registry information to specified entities and as provided by law.

The repeal of this rule is necessary because the subject matter has either been moved to another rule or is otherwise covered by statute.

Fiscal Impact

Current Program Numbers	Current Fee	Proposed Fee	Cumulative Amount
20,000 cardholders	\$5	\$30	\$25 increase = \$500,000
387 providers with ten or fewer cardholders	\$50	\$1,000	\$950 increase = \$367,650
222 providers with more than ten cardholders	\$50	\$5,000	\$4,950 increase = \$1,098,9000
Four testing laboratories	\$0	\$2,000	\$2,000 increase = \$8,000
137 chemical manufacturer endorsements	\$0	\$500	\$500 increase = \$68,500

Other Estimated Actions/Fees

1,400 licensee's employees		\$50	\$50 new fee = \$70,000
100 dispensaries		\$500	\$500 new fee = \$50,000
4,000 change requests		\$10	\$10 new fee = \$40,000

7. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., December 7, 2017.

8. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

9. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 7 above or may be made by completing a request form at any rules hearing held by the department.

10. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by electronic mail on October 26, 2017.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption, amendment, and repeal of the above-referenced rules will not significantly and directly impact small businesses.

/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 October 30, 2017.