BEFORE THE ALTERNATIVE HEALTH CARE BOARD DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

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In the matter of the adoption of NEW RULES I through IV and the amendment of ARM 24.111.502, 24.111.503, 24.111.511, 24.111.610, 24.111.611, and 24.111.2301 pertaining to midwife prescribing NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION AND AMENDMENT

TO: All Concerned Persons

1. On July 14, 2023, at 9:00 a.m., a public hearing will be held via remote conferencing to consider the proposed changes to the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:

- Join Zoom Meeting, https://mt-gov.zoom.us/j/85900234101
 Meeting ID: 859 0023 4101, Passcode: 914497
 -OR-
- b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656 Meeting ID: 859 0023 4101, Passcode: 914497

2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the department no later than 5:00 p.m., on July 7, 2023, to advise us of the nature of the accommodation that you need. Please contact the department at P.O. Box 1728, Helena, Montana 59624-1728; telephone (406) 444-5466; Montana Relay 711; or e-mail laborlegal@mt.gov.

3. <u>GENERAL REASONABLE NECESSITY</u>: The 2023 Montana Legislature passed Senate Bill (SB) 100 (revise laws on naturopaths and natural substances; eff. 4/24/2023), House Bill (HB) 392 (generally revise midwifery laws; eff. 10/1/2023), and HB 655 (require Medicaid to cover midwife-attended home births; eff. 7/1/2023). Accordingly, the Alternative Health Care Board (board) determined it is reasonably necessary to amend several rules and adopt four new rules to implement the three bills. Specifically, the rule changes will establish requirements for midwives to expand their administration of prescription medications, outline circumstances constituting low risk for planned home births, and update education requirements and prescribing abilities for naturopathic physicians. Where additional specific bases for a proposed action exist, the board will identify those reasons immediately following that rule.

4. The proposed new rules are as follows:

NEW RULE I EDUCATIONAL REQUIREMENTS FOR ADMINISTRATION

<u>OF DRUGS</u> (1) Midwives may become endorsed to obtain and administer prescription drugs per 37-27-302, MCA, by submitting an application that demonstrates the applicant either:

(a) holds the certified professional midwife (CPM) credential through MEAC accreditation (obtained after January 1, 2021); or

(b) completed both:

(i) an MEAC approved, pharmacology specific to midwives training course covering all drugs listed in the formulary of 37-27-302(2), MCA; and

(ii) an IV therapy course having a practical component that is:

(A) provided by the Montana Health Network;

(B) provided by MEAC; or

(C) another eight-hour course having a practical component.

AUTH: 37-1-131, 37-27-302, MCA IMP: 37-1-131, 37-27-302, MCA

NEW RULE II OBTAINING, STORING, AND DISPOSING OF DRUGS

(1) Endorsed midwives may obtain formulary drugs as allowed by law, including from:

(a) a person or entity licensed as a wholesale distributor by the Montana Board of Pharmacy; and

(b) a retail pharmacy, in minimal quantities for office use.

(2) Endorsed midwives must:

(a) store all formulary drugs in secure areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs; and

(b) dispose of drugs using means that are reasonably calculated to guard against unauthorized access by persons and harmful excretion of the drugs into the environment. The means that may be used include, without limitation:

(i) transferring the drugs to a reverse distributor who is registered to destroy drugs with the U.S. Drug Enforcement Agency;

(ii) removing the drugs from their original containers, mixing them with an undesirable substance such as coffee grounds or kitty litter, putting them in impermeable, non-descript containers such as empty cans or sealable bags, and throwing the containers in the trash; or

(iii) flushing the drugs down the toilet if the accompanying patient information instructs that it is safe to do so.

(3) Endorsed midwives may carry drugs to the home setting while providing care within the course and scope of the practice of midwifery.

AUTH: 37-1-131, 37-27-302, MCA IMP: 37-1-131, 37-27-302, MCA

<u>NEW RULE III USE OF FORMULARY DRUGS</u> (1) Endorsed midwives may use the drugs in 37-27-302(2), MCA, according to the following protocol describing the indication for use, dosage, route of administration, and duration of treatment:

Drug	Indication	Dose- in conformanc e ACOG guidelines	Route of Administratio n	Duration of Treatment
Oxygen	Maternal/Fet al Distress	10-12 L/min. 10 L/min.	Bag and mask Mask	Until maternal/fet al stabilization is achieved or transfer to hospital is complete
	Neonatal Resuscitation	10-12 L/min. 10 L/min.	Bag and mask Mask	Until stabilization is achieved or transfer to a hospital is complete
Oxytocin (Pitocin)	Postpartum hemorrhage only	10 Units/ml	Intramuscularl y only	1-2 doses Transport to hospital required if more than two doses are administered
Lidocaine HCI 2%	Local anesthetic for use during postpartum repair of lacerations or episiotomy	Maximum 50 ml	Percutaneous infiltration only	Completion of repair
Penicillin G (Recommended)	Group B Strep Prophylaxis	5 million units initial dose, then 2.5 million units every 4 hours until birth	IV in ≥ 100 ml LR, NS or D₅LR	Birth of baby
Methegrine (Methylergonovin e	Postpartum hemorrhage only	0.2mg/ml	Intramuscularl y only 1 dose	Transport to hospital required if single dose

				does not stop hemorrhage
Ampicillin Sodium (Alternative)	Group B Strep Prophylaxis	2 grams initial dose, then 1 gram every 4 hours until birth	IV in ≥100 ml NS or LR	Birth of baby
Cefazolin Sodium (drug of choice for penicillin allergy with low risk for anaphylaxis)	Group B Strep Prophylaxis	2 grams initial dose, then 1 gram every 8 hours	IV in ≥ 100 ml LR, NS or D₅LR	Birth of Baby
Clindamycin Phosphate (drug of choice for penicillin allergy with high risk for anaphylaxis)	Group B Strep Prophylaxis	900 mg every 8 hours	IV in ≥100 ml NS (not LR)	Birth of Baby
Epinephrine HCI 1:1000	Treatment or post- exposure prevention of severe allergic reactions	0.3 ml	Subcutaneousl y or intramuscularly	Every 20 minutes or until emergency medical services arrive Administer first dose then immediately request emergency services
Lactated Ringer's (LR) 5% Dextrose in Lactated Ringer's solution (D₅LR)	To achieve maternal stabilization	I - 2 liter bags First liter run in at a wide- open rate, the second liter titrated	Intravenously	Until maternal stabilization is achieved or transfer to a hospital is complete
		to client's condition	As directed	Birth of Baby

0.9% Sodium Chloride (NS) Sterile Water	Reconstitutio n of antibiotic powder	As directed		
Cytotec (Misoprostol)	Postpartum hemorrhage only	Up to 800 mcg	Rectally is the preferred method Orally is allowed	1-2 doses Transport to hospital required if more than one dose is administered
Rho(d) Immune Globulin	Prevention of Rho (d) sensitization in Rho (d) negative women	300 mcg	Intramuscularl y	Single dose at any gestation for Rho (d) negative, antibody negative women within 72 hours of spontaneous bleeding or abdominal trauma. Single dose at 26-28 weeks gestation for Rho (d) negative, antibody negative women Single dose for Rho (d) negative, antibody negative women Single dose for Rho (d) negative, antibody negative, antibody negative women within 72 hours of delivery of Rho (d)

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	Drankulavia			positive infant, or infant with unknown blood type
Phytonadione	Prophylaxis for Vitamin K Deficiency Bleeding			1 dose
0.5% Erythromycin Ophthalmic Ointment	Prophylaxis of Neonatal Ophthalmia	1 cm ribbon in each eye	Topical	1 dose
Tranexamic acid	Postpartum Hemorrhage	1000 mg over 10 minutes given within 3 hours of birth	Intravenous	Initiate transfer after administerin g first dose. If bleeding continues after 30 minutes or stops and restarts within 24 hours after the first dose, a second dose of 1000mg may be given.
Terbutaline	Stop or prevent premature labor	As per direct order of a licensed physician	As per direct order of a licensed physician	As per direct order of a licensed physician

AUTH: 37-1-131, 37-27-302, MCA IMP: 37-1-131, 37-27-302, MCA

<u>NEW RULE IV CIRCUMSTANCES CONSTITUTING A LOW RISK OF</u> <u>ADVERSE BIRTH OUTCOMES</u> (1) A low risk of adverse birth outcomes indicates a clinical scenario for which there is not clear demonstratable benefit for a medical intervention or transfer to a physician's care under ARM 24.111.610 or 24.111.611.

(2) Consultation with a physician as required by ARM 24.111.611(1)(a) does not preclude a low risk of adverse birth outcomes.

(3) Preexisting arrangements for emergency transportation to a nearby hospital if needed do not preclude a low risk of adverse birth outcomes.

AUTH: 37-1-131, 37-27-105, MCA IMP: 37-1-131, 37-27-105, MCA

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

<u>24.111.502 LICENSING BY EXAMINATION</u> (1) Applicants for naturopathic physician licensure by examination shall Each application for licensure must include:

(a) submit a completed application on a form furnished by the department together with the required fees;

(b) submit three letters of reference, at least one of which must be from a licensed naturopathic physician, attesting to the applicant's good moral character initial application fee;

(c) cause the naturopathic medicine college which conferred an N.D. or N.M.D. degree on the applicant to submit an official transcript of the applicant's naturopathic medicine education directly to the board office verification of the applicable education requirements; and

(d) cause the interstate reporting service of the North American Board of Naturopathic Examiners (NABNE) to submit directly to the board office, evidence of the applicant's passing score on proof of successful passage of the Naturopathic Physician Licensing Examination (NPLEX) as provided in (2).

(2) Except as provided in (5), <u>(3), all</u> applicants for naturopathic physician licensure in Montana must either <u>have passed</u>:

(a) have passed: Part I – Biomedical Science;

(i) all five individual basic science NPLEX examinations (Part I);

(ii) all eight individual clinical science NPLEX examinations (Part II) or passed the said Part II under the compensatory scoring model described in (3), prior to August 1, 2007;

(iii) the homeopathy NPLEX examination prior to February 1, 2008; and

(iv) the minor surgery NPLEX clinical examination; or

(b) have passed: Part II - Core Clinical Science;

(i) all five individual basic science NPLEX examinations (Part I);

(ii) the single integrated NPLEX Part II - Core Clinical Science Examination;

and

(iii) the minor surgery NPLEX clinical examination; or

(c) have passed: Part II – Clinical Elective Pharmacology Examination; and

(i) the single integrated NPLEX Part I - Biomedical Science Examination;

(ii) the single integrated NPLEX Part II - Core Clinical Science Examination;

and

(iii) the minor surgery NPLEX clinical examination.

(d) Part II – Clinical Minor Surgery Examination.

(3) A minimum converted score of 75 is required to pass the Part I -

Biomedical Science Examination. A minimum converted score of 75 is required to pass the Part II - Core Clinical Science Examination. A minimum converted score of

75 is required to pass the minor surgery examination. A minimum converted score of 75 is required to pass the homeopathy examination. The converted score is a scaled score and not a percentage. The board will accept the compensatory scoring model for the eight individual clinical science NPLEX examinations under (2)(a)(ii) provided all eight examinations were taken prior to August 1, 2007.

(4) Applicants shall contact NABNE for NPLEX test dates and locations. NABNE may be contacted at 9220 SW Barbur Blvd., Suite 119, #321, Portland, OR 97219-5434, (503) 778-7990, or via the Internet at www.nabne.org.

(5) (3) An applicant seeking licensure under this rule based upon a licensure examination other than the NPLEX shall submit proof satisfactory to the board of the applicant's score on the examination, the score deemed passing by the examination's developer, and the examination's acceptance by a licensing authority in any other state or territory of the United States, the District of Columbia, or a foreign country. Upon receipt, the board will determine whether to prescribe or endorse the proffered examination pursuant to its authority under 37-26-201 and 37-26-402, MCA, based upon the examination's substantial equivalency to the NPLEX examination examinations listed in (2) may apply to the board for acceptance of a substantially equivalent examination.

AUTH: 37-1-131, 37-26-201, MCA IMP: 37-1-131, 37-26-402, 37-26-403, MCA

<u>REASON</u>: With the expanded prescribing authority granted to NDs by 2023's SB 100, the board determined it is reasonably necessary to update the examination requirements to include a specific examination in pharmacology for new applicants. The board is also amending this rule to update and reflect the exams NABNE currently offers, and repeal outdated exams.

Further, the board is repealing unnecessary requirements in the application process, such as letters of reference, and updating processes for submitting transcripts and reporting examination scores. Good moral character is shown through the applicant's responses to the application questions, and transcript and exam submission requirements are addressed in streamlined and standardized application procedures for all licensing boards and programs. It is unnecessary to specify in board rule the exact steps to vetting application requirements.

<u>24.111.503 LICENSING OF APPLICANTS BY ENDORSEMENT</u> (1) A license to practice as a naturopathic physician in the state of Montana may be issued without examination to an applicant <u>who</u>:

(a) who has submitted a completed application and correct fee; and

(b) who graduated and holds a degree/diploma from an approved naturopathic medical college that prepares candidates for licensure as a naturopathic physician, provided that such program, at the time of the candidate's graduation, is equivalent to or exceeds the minimum naturopathic medical educational standards required by the board's laws and rules;

(c) (b) who holds a current unencumbered license to practice as a naturopathic physician in another state or jurisdiction; whose laws and rules are substantially equivalent to Montana's. Applicants from another jurisdiction who have

not passed the Naturopathic Physician Licensing Examination (NPLEX) Part II – Clinical Elective Pharmacology Examination will be required to do so prior to licensure.

(d) who is of good moral character as evidenced by three letters of reference at least one of which must be from a licensed naturopathic physician; and

(e) who has passed a naturopathic physician licensure examination in another state or jurisdiction meeting or exceeding the requirements of ARM 24.111.502(2) and (3) or (5).

(2) It is the applicant's responsibility to cause the licensing authority of the state or jurisdiction from which the applicant is endorsing to send official verification of licensure directly to the board.

(3) It is the applicant's responsibility to cause the naturopathic medical college that conferred the applicant's N.D. or N.M.D. degree to send an official transcript of the applicant's naturopathic medical education directly to the board.

(4) It is the applicant's responsibility to cause verification of passing scores on the NPLEX or other licensing examination used to qualify for initial licensure in another state or jurisdiction, to be reported directly to the board by the official score reporting service utilized by the examination owner.

AUTH: 37-1-131, 37-26-201, MCA IMP: 37-1-131, 37-1-304, MCA

<u>REASON</u>: The board is amending this rule on licensure by endorsement following the passage of SB 100, which allows for expanded prescribing by naturopathic physicians. In enacting the legislation, the Legislature requested the board consider requiring specific pharmacology education for licensees new to practicing in Montana. The board is therefore amending this rule to require applicants licensed in other jurisdictions to successfully pass the pharmacology portion of the NPLEX if the applicant has not previously done so.

Further, the board is repealing unnecessary requirements in the application process, such as letters of reference, and updating processes for license verification, transcript submission, and reporting examination scores. Good moral character is shown through the applicant's responses to the application questions. Application requirements are determined for all licensing boards and programs through streamlined and standardized application procedures. It is unnecessary to specify in board rule the exact steps to vetting application requirements.

24.111.511 NATUROPATHIC PHYSICIAN NATURAL SUBSTANCE FORMULARY LIST (1) Except as provided in (2), naturopathic physicians may prescribe and, administer, for preventive and therapeutic purposes the drugs listed in this natural substance formulary list as provided for in 37-26-301, MCA. and dispense pursuant to 37-2-104, MCA:

(a) all legend drugs;

(b) with a DEA registration, all drugs in Schedules II-V as listed at 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, and ARM 24.174.1412;

(c) all biological substances including extracts and/or their products and residues;

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(d) topical preparations;

(e) vitamins, minerals, trace minerals, enzymes, and food;

(f) homeopathic preparations;

(g) laboratory and diagnostic procedures;

(h) all amino acids and amino acid combinations;

(i) barrier contraceptives;

(j) all botanical extracts and their derivatives;

(k) electrolytes and fluid replacement;

(I) expectorants and mucolytics;

(m) hormones;

(n) liver preparations; and

(o) childbirth preparations.

(2) Naturopathic physicians may <u>not</u> prescribe and administer all amino acids and amino acid combinations. The following are examples:

(a) alanine general anesthetics;

(b) arginine mifepristone and misoprostol as an abortifacient;

(c) aspartic acid; barbiturates, except:

<u>(i) phenobarbital;</u>

(ii) butalbital; and

<u>(iii) primidone;</u>

(d) cystine; <u>systemic oncology agents, except antineoplastic agents, in oral</u> and topical form only:

(i) 5fu;

(ii) anastrozole;

(iii) letrozole;

(iv) mechlorethamine;

(v) megestrol;

(vi) mercaptopurine;

(vii) methotrexate;

(viii) tamoxifen; and

(ix) tretinoin; and

(e) glutamic acid; ketamine.

(f) glycine;

(g) histidine;

(h) hydroxyproline;

(i) isoleucine;

(j) leucine;

(k) levocarnitine;

(I) lysine;

(m) methionine;

(n) N-acetyl cysteine;

(o) phenylalanine;

(p) proline;

(q) serine;

(r) threonine;

(s) tryptophan; and

(t) valine.

(3) Naturopathic physicians may prescribe and administer antimicrobials. Naturally derived examples are:

(a) antifungal agents:

(i) fluconazole;

(ii) gentian violet;

(iii) griseofulvin;

(iv) itraconazole;

(v) ketoconazole for topical use;

(vi) metronidazole;

(vii) nystatin; and

(viii) terninafine;

(b) cephalosporin derivatives:

(i) cefaclor;

(ii) cefadroxil;

(iii) cefdinir;

(iv) cefixime;

(v) cefpodoxime;

(vi) cefprozil;

(vii) ceftibuten;

(viii) ceftriaxone;

(ix) cephradine; and

(x) loracarbef;

(c) erythromycin and its salts:

(i) azithromycin;

(ii) clarithromycin; and

(iii) nitromide;

(d) penicillins:

(i) amoxicillin;

(ii) amoxicillin clavulanate;

(iii) ampicillin;

(iv) cloxacillin;

(v) dicloxacillin;

(vi) penicillin G; and

(vii) penicillin VK;

(e) tetracyclines:

(i) doxycycline;

(ii) minocycline; and

(iii) oxytetracycline;

(f) nitrofuran derivatives:

(i) nitrofurantoin;

(g) sulfonamide derivatives:

(i) sulfamethoxazole; and

(ii) trimethoprim/sulfamethoxazole;

(h) quinolones:

(i) ciprofloxacin; and

(ii) levaquin.

(4) Naturopathic physicians may prescribe and administer barrier contraceptives.

(5) Naturopathic physicians may prescribe and administer all botanical extracts and their derivatives -- prescription and nonprescription substances -- as exemplified in traditional botanical and herbal pharmacopeia. These are to be used at accepted therapeutic dosages, which means a dose which by its actions on organs does not impair function or destroy human life. The following are examples:

(a) belladonna;

(i) atropine, atropine sulfate;

(b) carnivora;

(c) cineraria maritima;

(d) codeine salts;

(e) colchicine;

(f) ephedra:

(i) ephedrine; and

(ii) pseudoephedrine;

(g) ergot:

(i) ergonovine;

(iii) ergotamine tartrate; and

(iii) methylergonovine;

(h) glycerrhiza (licorice);

(i) hydrocodone;

(j) hyoscamus:

(i) hyoscyamine sulfate;

(ii) hyoscyamine; and

(iii) scopolamine;

(k) morphine;

(I) nicotine preparations;

(m) oxycodone;

(n) paregoric;

(o) pilocarpine;

(i) physostigmine;

(p) quinine;

(q) rauwolfia serpentina;

(r) salicylate salts;

(s) sarapin;

(t) theophylline;

(u) thiosinimum;

(v) tramadol;

(w) viscum album:

(i) iscador; and

(ii) iscucin; and

(x) yohimbine HCL.

(6) Naturopathic physicians may prescribe and administer electrolytes and fluid replacement. The following are examples:

(a) dextrose solutions;

(b) lactated Ringer's solution;

(c) Ringer's solution;

(d) saline solutions; and

(e) sterile water for injection.

(7) Naturopathic physicians may prescribe and administer expectorants and mucolytics. The following are examples:

(a) acetyl cysteine;

(b) guaiacol;

(c) iodinated glycerol; and

(d) potassium iodide.

(8) Naturopathic physicians may prescribe and administer enzyme, digestive, and proteolytic preparations. The following are examples:

(a) amylase;

(b) chymotrypsin;

(c) hyaluronidase;

(d) lipase;

(e) pancreatin;

(f) pancrelipase;

(g) papain;

(h) secretin; and

(i) trypsin.

(9) Naturopathic physicians may prescribe and administer homeopathic preparations - all prescription and nonprescription remedies.

(10) Naturopathic physicians may prescribe and administer hormones. The following are examples:

(a) adrenal:

(i) adrenal cortical extract;

(ii) cortisol;

(iii) cortisone;

(iv) DHEA;

(v) epinephrine;

(vi) pregnenolone; and

(vii) prednisone;

(b) calcitonin;

(c) glucogon;

(d) gonadal:

(i) estrogens:

(A) conjugated estrogens;

(B) estradiol;

(C) estriol;

(D) estrone;

(E) estropipate;

(F) ethynyl estradiol;

(G) mestranol; and

(H) quinestrol;

(ii) progesterones:

(A) medroxyprogesterone acetate;

(B) norenthindrone and salts;

(C) progesterones; and

(D) progestogens; and

(iii) testosterone and its salts;

(e) insulin;

(f) pituitary hormones:

(i) ACTH;

(g) thymus; and

(h) thyroid USP:

(i) levothyroxine; and

(ii) liothyronine;

(i) thyroglobulin USP.

(11) Naturopathic physicians may prescribe and administer liver preparations. The following is an example:

(a) trinsicon.

(12) Naturopathic physicians may prescribe and administer all prescription and nonprescription minerals, trace metals and their derivatives. The following are examples:

(a) boron;

(b) calcium compounds;

(c) calciumedetate sodium;

(d) copper compounds;

(e) fluoride compounds;

(f) iodine:

(i) potassium iodide; and

(ii) niacinamide hydroiodide;

(g) iron salts;

(h) magnesium compounds;

(i) potassium compounds;

(j) silver nitrate; and

(k) trace mineral compounds:

(i) chromium;

(ii) selenium;

(iii) molybdenum;

(iv) vanadium; and

(v) zinc compounds.

(13) Naturopathic physicians may prescribe and dispense the following miscellaneous drugs:

(a) albuterol;

(b) anticoagulants:

(i) heparin; and

(ii) warfarin;

(c) bile salts and acids:

(i) chenodiol;

(ii) cholic acid;

(iii) chenodeoxycholic acid;

(iv) dehydrocholic acid;

(v) ursodeoxycholic acid; and

(vi) ursodiol;

(d) biological agents:

(i) urea; and

(ii) bee venom;

(e) botox cosmetic;

(f) digestive aids:

(i) betaine HCL; and

(ii) glutamic HCL agents;

(g) DMSO, DMSA, DMPS;

(h) juvederm;

(i) lisinopril;

(j) metformin;

(k) misoprostol;

(I) oxygen;

(m) pyridium and pyridium plus;

(n) salicylic acid; and

(o) vaccines.

(14) Naturopathic physicians may prescribe and administer vitamins, including all prescription and nonprescription vitamin preparations and their derivatives. The following are examples:

(a) ascorbic acid (vitamin C);

(b) biotin;

(c) cyanocobalamin (vitamin B₁₂):

(i) hydroxocobalamin, including intrinsic factor;

(d) folic acid;

(e) niacin (vitamin B₃);

(f) pantothenic acid (vitamin B₅):

(i) dexpanthenol;

(g) phosphatidylcholine;

(h) pyridoxine (vitamin B₆);

(i) riboflavin (vitamin B₂);

(j) thiamin (vitamin B₁);

(k) vitamin A:

(i) betacarotene and derivatives;

(İ) vitamin D:

(i) calcitrol;

(ii) cacifediol;

(iii) dovonex; and

(iv) ergocalciferol;

(m) vitamin E; and

(n) vitamin K:

(i) menadiol.

(15) Naturopathic physicians may prescribe and administer childbirth preparations. The following are examples:

(a) methergine;

(b) pitocin - IM injection;

(c) Rh immune globulin; and

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(d) triple dye.

(16) Naturopathic physicians may prescribe and administer topical medicines. The following are examples:

(a) debridement/escharotic agents:

(i) podophyllum resin;

(ii) podofilox 0.5 percent solution;

(iii) urea cream 40 percent; and

(iv) trichloralacitate (TCA);

(b) miscellaneous topical agents:

(i) selenium sulfide; and

(ii) hydrocortisone;

(c) salicylic acid;

(d) scabicides and pediculoses - lindane, permethrin or whichever agent is the current recommended treatment for these infections;

(e) topical antibiotics:

(i) silver sulfadiazine cream; and

(ii) mupirocin;

(f) topical and local anesthetics:

(i) ethyl chloride spray;

(ii) fluro-ethyl spray;

(iii) fluro-methane spray;

(iv) lidocaine HCL; and

(v) procaine HCL.

(17) (3) The licensed pharmacist member of the formulary committee formed pursuant to 37-26-301, MCA, shall serve on the committee for a four-year term unless the pharmacist resigns, or is replaced by vote of the board.

AUTH: 37-1-131, 37-26-201, MCA IMP: 37-1-131, 37-26-301, MCA

<u>REASON</u>: Senate Bill 100 removed the requirement that a substance be of a natural origin in order to be prescribed by a naturopathic physician. The board is amending this formulary rule to implement the legislative changes. Further, the board is amending the rule to provide the drugs naturopathic physicians may not prescribe, rather than the current extensive laundry list of the many therapies within an ND's scope of practice. The board concluded this format will reduce confusion among licensees, pharmacists, and the public as to the appropriate therapies for an ND to prescribe.

<u>24.111.610 HIGH RISK PREGNANCY: CONDITIONS REQUIRING</u> <u>PRIMARY CARE BY A PHYSICIAN</u> (1) If the following conditions are present, the licensed direct-entry midwife shall not accept the woman as a client:

(a) and (a)(i) remain the same.

(ii) diabetes mellitus (Class II or greater) requiring medication;

(iii) through (viii) remain the same.

(ix) active: tuberculosis, syphilis, gonorrhea, strep B, hepatitis, AIDS, genital herpes at onset of labor;

(x) through (c) remain the same.

AUTH: 37-27-105, MCA IMP: 37-27-105, MCA

<u>REASON</u>: The board is amending (1)(a)(ii) to correct an error in referring to diabetes mellitus as having classes, and instead clarify that diabetes mellitus requiring medication indicates a high risk pregnancy.

The board is amending (1)(a)(ix) to implement HB 392 by reflecting that direct-entry midwives with a medication endorsement can now treat patients with streptococcus B.

24.111.611 CONDITIONS WHICH REQUIRE PHYSICIAN CONSULTATION OR TRANSFER OF CARE (1) If the following conditions are present in a client, the direct-entry midwife shall attempt to consult a physician and/or transfer care to a physician. A certified nurse midwife or licensed direct-entry midwife shall also be consulted if appropriate attempts to consult a physician have been unsuccessful. Documentation of the condition, recommendation (including continuation of care by the licensed direct-entry midwife, if appropriate) and treatment must be maintained in the client records. Conditions include, but are not limited to the following:

(a) through (b)(viii) remain the same.

(ix) <u>uncontrolled</u> maternal hemorrhage uncontrolled by IM Pitocin;

(x) through (c) remain the same.

AUTH: 37-27-105, MCA IMP: 37-27-105, MCA

<u>REASON</u>: The board is amending (1)(b)(ix) to implement HB 392 by reflecting that direct-entry midwives with a medication endorsement can now use medications other than intramuscular Pitocin to treat postpartum hemorrhage.

<u>24.111.2301</u> UNPROFESSIONAL CONDUCT (1) The board defines unprofessional conduct for naturopathy and midwifery as follows:

(a) through (f) remain the same.

(g) practicing naturopathy or midwifery while the license is suspended, revoked, or expired;

(h) through (l) remain the same.

(m) failure by a midwife to maintain current and valid certifications in adult and infant cardiopulmonary resuscitation as provided by 37-27-201, MCA-; (n) prescribing a scheduled drug without a surrent DEA registration

(n) prescribing a scheduled drug without a current DEA registration.

AUTH: 37-1-131, 37-1-319, 37-26-201, 37-27-105, MCA IMP: 37-1-141, 37-1-316, 37-1-319, 37-26-201, 37-27-105, MCA

<u>REASON</u>: The board is amending (1)(g) so the provision applies to all licensees under the board's jurisdiction. The board is adding (1)(n) to align with amendments

to the formulary rule, ARM 24.111.511, that provide that naturopathic physicians prescribing controlled substances must be DEA registered.

6. Concerned persons may present their data, views, or arguments at the hearing. Written data, views, or arguments may also be submitted at dli.mt.gov/rules or P.O. Box 1728; Helena, Montana 59624. Comments must be received no later than 5:00 p.m., July 21, 2023.

7. An electronic copy of this notice of public hearing is available at dli.mt.gov/rules and sosmt.gov/ARM/register.

8. The agency maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the agency. Persons wishing to have their name added to the list may sign up at dli.mt.gov/rules or by sending a letter to P.O. Box 1728; Helena, Montana 59624 and indicating the program or programs about which they wish to receive notices.

9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsors were contacted on May 1, 2023, by electronic mail.

10. Pursuant to 2-4-111, MCA, the agency has determined that the rule changes proposed in this notice will not have a significant and direct impact upon small businesses.

11. Department staff has been designated to preside over and conduct this hearing.

ALTERNATIVE HEALTH CARE BOARD ALISUN BONVILLE, ND, CHAIR

<u>/s/ DARCEE L. MOE</u> Darcee L. Moe Rule Reviewer <u>/s/ LAURIE ESAU</u> Laurie Esau, Commissioner DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State June 13, 2023.