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

tattooing)	In the matter of the adoption of NEW RULES I through III and the amendment of ARM 37.112.102, 37.112.103, 37.112.108, 37.112.116, 37.112.117, 37.112.121, 37.112.125, 37.112.129, 37.112.131, 37.112.132, 37.112.133, 37.112.137, 37.112.141, 37.112.142, 37.112.144, 37.112.147, 37.112.151, 37.112.152, 37.112.156, 37.112.157, 37.112.158, 37.112.163, 37.112.165, and 37.112.167 pertaining to body piercing and	 NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION AND AMENDMENT))<!--</th-->
	pertaining to body piercing and tattooing))

TO: All Concerned Persons

- 1. On January 9, 2025, at 9:00 a.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed adoption and amendment of the above-stated rules. Interested parties may access the remote conferencing platform in the following ways:
- (a) Join Zoom Meeting at: https://mt-gov.zoom.us/j/84904626492?pwd=x5viOoj88XiegMbJpRvTNjsmlzgW34.1, meeting ID: 849 0462 6492, and password: 190652; or
- (b) Dial by telephone: +1 646 558 8656, meeting ID: 849 0462 6492, and password: 190652. Find your local number: https://mt-gov.zoom.us/u/kb55Ttqhc.
- 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 December 26, 2024, to advise us of the nature of the accommodation that you need. Please contact Bailey Yuhas, 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 hhsadminrules@mt.gov.
 - 3. The rules as proposed to be adopted provide as follows:

NEW RULE I JEWELRY STANDARDS FOR INITIAL BODY PIERCINGS

- (1) All materials used for an initial body piercing must meet ASTM and/or ISO standards for implantation. Examples of allowable materials include:
 - (a) steel that is ASTM F138 compliant or ISO 5832-1 compliant;
 - (b) steel that is ISO 10993-6, 10993-10, and/or 10993-11 compliant:

- (c) unalloyed titanium that is ASTM F67 or ISO 5832-2 compliant;
- (d) alloyed titanium (Ti6Al4V ELI) that is ASTM F136 compliant or ISO 5832-3 compliant;
- (e) alloyed titanium (Ti6Al7Nb ELI) that is ASTM F1295 compliant or ISO 5832-11 compliant; and
- (f) any polymer or plastic material that is ISO 10993-6, 10993-10, and/or 10993-11 compliant and/or meets the U.S. Pharmacopeia (USP) Class VI classification, including polytetrafluoroethylene (PTFE) that is ASTM F754 compliant.
- (2) Gold jewelry must be comprised of solid 14 karat or higher yellow, white, or rose gold that is nickel free and cadmium free. Gold jewelry may not be:
- (a) plated, unless using materials approved by the department or local health authority that is solid 14 karat or higher yellow, white, or rose gold that is nickel free and cadmium free:
 - (b) gold filled; or
 - (c) gold overlay/vermeil.
- (3) Platinum jewelry must be comprised of solid unalloyed or alloyed platinum that is nickel free and cadmium free.
- (4) Niobium jewelry must be comprised of unalloyed niobium (Nb) that is ASTM B392 compliant. This includes commercial grade 2 niobium and commercial grade 4 niobium that contains 1% zirconium.
- (5) Glass jewelry must be lead free. Examples of permissible glass jewelry materials include:
 - (a) fused quartz;
 - (b) borosilicate; and
 - (c) soda-lime.
- (6) All threaded or press-fit jewelry must have internal tapping. Threads on exterior of posts and barbells are not permitted.
- (7) Jewelry surfaces and ends must be smooth and free of nicks, scratches, burrs, stamps, hallmarks, and polishing compounds.
- (8) Jewelry metals must have a consistent mirror finish on surfaces that frequently come in contact with tissue.
- (9) All jewelry used for initial piercing on persons older than 12 years of age must be ASTM F2999 compliant.
- (10) All jewelry used for initial piercing on persons 12 years of age or younger must be ASTM F2923 compliant.
- (11) Receipts for jewelry purchased for initial piercings must include the specifications for items sold in accordance with the standards set forth in (1). Receipts must be retained by the establishment for at least three years, kept on the premises for at least one year, and made available to the department or the local health authority upon request.
- (12) Material certificates from jewelry suppliers for jewelry used for initial piercings must include the name of the purchaser of material, the name of the seller of the material, the date of material sales, the type of material purchased, the composition of material purchased, the quantity of material purchased, and the country of origin. Records must:
 - (a) be updated from the supplier for each new lot of material; and

(b) be retained by the establishment for a minimum of three years, kept on the premises for a minimum of one year, and made available to the department or the local health authority upon request.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

NEW RULE II BRANDING SAFETY AND SANITATION REQUIREMENTS

- (1) The work room must have walls that extend to the ceiling and a closeable door.
- (2) A branding work room must be equipped with an ultraviolet air purifier appropriately sized to the room based on the square footage and the manufacturer's recommendations.
- (3) Any person present during the branding procedure, including all personnel and the client, must wear a mask rated as N-95 or higher.
- (4) Body artists must use the process of "strike branding" or use a thermal cautery unit (TCU).
 - (5) Only nongalvanized metal may be used for "strike branding."
- (6) Body artists must use only propylene gas to heat the metal for "strike branding."

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

NEW RULE III SCARIFICATION SAFETY AND SANITATION

<u>REQUIREMENTS</u> (1) The body artist must wear personal protective equipment (PPE) consisting of disposable sleeves .

- (2) The scarification work room must have walls that extend to the ceiling and a closeable door.
- (3) The scarification work room must be equipped with an ultraviolet air purifier appropriately sized to the room based on the square footage and the manufacturer's recommendations.
- (4) The body artist must wear sterile gloves when coming into contact with sterile equipment during the procedure.

- 4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:
- 37.112.102 PURPOSE (1) The rules in this chapter pertain to tattooing and body piercing body art establishments under Title 50, chapter 48, MCA, that are licensed by the Montana Department of Public Health and Human Services. Unless otherwise specified by the rules of the local health authority, the rules in this chapter do not apply to tattooing and body piercing body art establishments that are licensed solely by local boards of health pursuant to 50-48-203, MCA.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-203, MCA

- 37.112.103 DEFINITIONS In addition to the definitions contained in 50-48-102, MCA, the following definitions apply to this subchapter:
- (1) "Aftercare instructions" means verbal and written instructions that the client should follow to prevent infection and promote healing of the skin after receiving a tattoo or body piercing body art procedure.
- (2) "Antiseptic" means a substance applied to the skin that kills or inhibits the growth of disease-causing microorganisms. product that is labeled as useful in preventing diseases caused by microorganisms present on the skin and/or on mucosal surfaces of humans. This includes products meant to kill germs and/or labeled as "antiseptic," "antimicrobial," "antibacterial," "microbicide," "germicide," or other similar terms.
 - (3) "Artist" means a tattooist or body piercer.
 - (4) remains the same but is renumbered (3).
- (4) "Autoclave" means a device that is intended for use by a user to sterilize products by means of pressurized steam. This device must comply with one of three types of steam programs defined as B, N, and S by standard EN13060, ISO 17665.
- (5) "Automated instrument washer" means a mechanical washer designed specifically for the decontamination of instruments prior to sterilization. These devices must comply with ISO 158831/2.
- (6) "Blood-borne pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- (7) "Body art" means body piercing and tattooing. The term includes ear lobe piercing, branding and scarification.
- (8) "Body artist" means any person aged 18 or older performing body art services.
 - (5) remains the same but is renumbered (9).
- (6) "Body piercer" means a person who engages in the practice of piercing as defined in 50-48-102. MCA.
- (7) "Body piercing establishment" means any room, space, shop, or salon, including a temporary or mobile facility, where body piercing is practiced.
- (10) "Branding" means the process in which a mark or marks are burned into human skin tissue with the intention of leaving a permanent mark.
 - (8) remains the same but is renumbered (11).
- (9)(12) "Client" means the person whose skin will be tattooed or pierced an individual on whom a body artist performs a body art procedure.
- (10)(13) "Contaminated" means the probable presence of disease-causing microorganisms blood or other potentially infectious materials on an item or surface.
- (11) "Department" means the Department of Public Health and Human Services.
 - (12) through (18) remain the same but are renumbered (14) through (20).

- (19)(21) "Instrument" means hand piece, needle, and any other tool that may come in contact with a client's body or be exposed to blood or body fluids during a tattooing or body piercing body art procedure.
- (20)(22) "Jewelry" means any ornament designed for insertion into a pierced area of a client biocompatible object that is worn through a body piercing.
- (23) "Material certificate" means all documents intended to state the specifics of a material used for body jewelry. Names for these documents include but are not limited to mill certificates, material certificates, metal composition sheets, MSD, and material certification sheets.
- (21)(24) "Microdermal anchor" means a piece of jewelry defined in ARM 37.112.103(16) used for single-point piercings that has a foot no larger than 8mm in length.
- (22)(25) "Mobile establishment" means a <u>licensed</u> facility where tattooing or body piercing or both body art is conducted, utilizing a wheeled vehicle for movement from place to place.
- (23)(26) "Operator" means any owner of an establishment or any person who is responsible for the establishment as well as the other <u>body</u> artists working at the establishment, for the purpose of meeting the requirements of this chapter.
- (24)(27) "Permanent cosmetics", also known as permanent makeup or micropigmentation, means tattooing any part of the face for cosmetic purposes a tattoo, whether permanent or semipermanent, which is applied to a body part, including eyebrows, eyelids, lips, and other parts of the body for beauty marks, hair imitation, lash enhancement, or areola repigmentation. This term also includes procedures commonly referred to as permanent makeup, micropigmentation, micropigment implantation, microblading, dermagraphics, cosmetic tattooing, and other similar types of procedures.
 - (25) remains the same but is renumbered (28).
- (29) "Piercing gun" means a device approved by the department that pierces an individual's ear lobe using a single-use stud and clasp ear piercing system.
 - (26) remains the same but is renumbered (30).
- (31) "Scarification" means the process in which a mark or marks are cut into human skin tissue with the intention of leaving a permanent mark.
 - (27) and (28) remain the same but are renumbered (32) and (33).
- (29)(34) "Single-use" means items that are intended to be used once then discarded products or items that are intended for one-time, one-person use and that are disposed of after use on a client, including cotton swabs or cotton balls, tissues or paper products, paper or plastic cups, gauze and sanitary coverings, razors, needles, scalpel blades, stencils, ink cups, and protective gloves.
 - (30) remains the same but is renumbered (35).
- (36) "Strike branding" means the process by which a mark is burned with heated metal into the tissue of a person.
 - (31) remains the same but is renumbered (37).
- (32) "Tattoo establishment" means any room, space, shop, or salon, including a temporary or mobile facility, where tattooing is practiced.
- (33)(38) "Tattooist" means a person who engages in the practice of tattooing as defined in 50-48-102, MCA.

- (34)(39) "Temporary establishment" means a facility where either tattooing or body piercing or both are body art is conducted for not more than 14 days at one location in a calendar year.
- (35)(40) "Transdermal anchor" means a piece of jewelry defined under ARM 37.112.103(16) used for single-point piercings that has a foot larger than 8mm in length.
 - (36) and (37) remain the same but are renumbered (41) and (42).
- (43) "Ultrasonic unit" means a device that removes debris by a process called cavitation, in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces.
 - (38) remains the same but is renumbered (44).
- (39)(45) "Work room" means a designated room or area in which either tattooing or body piercing body art takes place. The work room includes the client chair or table, counter, mayo stand, instrument tray, storage drawer, and body artist's chair.

AUTH: 50-48-103, MCA

IMP: 50-48-102, 50-48-103, MCA

- <u>37.112.108 GENERAL FACILITY REQUIREMENTS</u> (1) through (3) remain the same.
- (4) An establishment may not be operated in any room or area used as living or sleeping quarters, including bathroom or handwashing sink areas. An establishment must be separated from any living or sleeping quarters by solid self-closing doors. Access to the establishment must be separate from access to living areas.

- 37.112.116 TOILETS AND HANDWASHING SINKS FACILITIES (1) Each establishment must have a toilet and handwashing facility sink conveniently available to clients and body artists during all hours of operation.
 - (2) through (4) remain the same.
- (5) Equipment and supplies used for either tattooing or body piercing or both body art procedures must not be stored or used within the toilet room.
- (6) The handwashing facility sink must be located either within the toilet room or within ten feet of the toilet room door.
 - (7) through (10) remain the same.
- (11) Each handwashing sink must be provided with individual, disposable single-use towels that are kept clean for drying hands and a waste receptacle. Non-disposable single-use towels may be used, subject to the following requirements:
 - (a) the towels must be mechanically washed and hot air dried;
- (b) the wash cycle must run with sufficient detergent and for a time demonstrated to thoroughly remove all visible soil;
- (c) the towels must be thoroughly hot air tumble dried to at least 130°F (54°C) for ten minutes; and

(d) laundered towels must be kept protected from contamination from soiled laundry and other sources by using separate labeled carts or containers for transportation, by providing sufficient space for sorting, folding, and storage, and by washing hands between touching soiled and clean laundry.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

- <u>37.112.117 WORK ROOM REQUIREMENTS</u> (1) All tattooing and body piercing body art procedures must take place in the work room only.
 - (2) and (3) remain the same.
- (4) Animals are not allowed in the work room, except for patrol dogs accompanying security or police officers and service animals such as guide dogs. Fish aquariums are allowed in waiting rooms and areas outside of the work room. Fish aquariums may contain only aquatic species that can survive underwater for a minimum of 48 hours.
 - (5) through (7) remain the same.
- (8) The work Work rooms must have at least one handwashing facility sink unless there is a handwashing facility sink outside the work room within ten feet of the work room door.
- (a) If any client chair is more than fifteen feet from a handwashing sink, additional sinks may be required within the work room.
- (a)(b) If the handwashing facility sink is outside the work room, the work room door must be a two-way self-closing door. The two-way self-closing door may be a solid door, swinging café door, or curtain.
 - (b)(c) The handwashing facility sink cannot be in the same room as the toilet.
 - (c) remains the same but is renumbered (d).
- (d)(e) The handwashing sink must be sanitized with an EPA-certified disinfectant at least once at the beginning of each day while the establishment is in operation.
 - (e) through (i) remain the same but are renumbered (f) through (j).
 - (9) remains the same.
- (a) Waste receptacles must be covered except while in use to prevent contamination of hands and gloves. <u>lined and covered</u>. The receptacles must be <u>cleanable</u>, <u>kept clean</u>, and have self-closing lids with hands-free controls.
- (b) Waste receptacles in the work room must be emptied daily <u>or more often</u>, as needed.
 - (c) through (11) remain the same.
- (12) Tobacco use, <u>vaping</u>, eating, or drinking is prohibited in the work room, except eating and drinking is allowed when needed for first aid purposes.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

<u>37.112.121 TEMPORARY OR MOBILE ESTABLISHMENT</u> (1) through (3) remain the same.

- (4) Mobile establishments, such as a trailer, mobile home, or mobile vehicle, must have four solid walls. Outdoor tents are prohibited.
- (5) The venue for a temporary event must be approved by the department or local health authority prior to the event. The venue must be indoors and meet all requirements of ARM 37.112.117.
- (6) Temporary or mobile establishments must be used solely for the purpose of body art procedures. Food prep and habitation are prohibited.
- (7) The use of an autoclave is prohibited in temporary or mobile establishments. All equipment must be individually wrapped and sterile or sterilized at the time of use with a cassette sterilization unit.

- 37.112.125 EQUIPMENT AND SUPPLIES (1) through (7) remain the same.
- (8) Disinfectants, cleaning compounds, pesticides, and other chemicals must be stored in such a manner that prevents contamination of equipment, supplies, and work surfaces. Chemical containers must be clearly labeled with the common name of the material. Chemicals must be used in a manner consistent with the manufacturer's labeling.
- (9) Chemical containers must be clearly labeled with the common name of the material. Chemicals must be used in a manner consistent with the manufacturer's labeling.
 - (9) remains the same but is renumbered (10).
- (10)(11) Tables, trays, <u>machinery, tools, containers, and all other equipment</u> used by each individual body artist and equipment may not be shared among <u>body</u> artists serving different clients at the same time.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

37.112.129 BLOOD-BORNE PATHOGEN EXPOSURE CONTROL (1) An establishment operator employing at least one <u>body</u> artist shall meet the applicable requirements of 29 CFR 1910.1030, which provides standards for blood-borne pathogen exposure control as promulgated by the U.S. Department of Labor, Occupational Safety and Health Administration. The department hereby adopts and incorporates by reference 29 CFR 1910.1030, <u>as amended May 14, 2019</u>. Copies of 29 CFR 1910.1030 this federal regulation may be obtained by contacting the Montana Department of Public Health and Human Services, Public Health and Safety Division, Food and Consumer Environmental Health and Food Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951 or by visiting https://www.ecfr.gov/.

- 37.112.131 STERILIZATION OF EQUIPMENT AND JEWELRY (1) All nondisposable instruments used for tattooing or body piercing body art that can come into contact with blood or body fluids must be individually wrapped and sterilized by an autoclave. All disposable instruments that come into contact with blood or body fluids must come from the supplier individually wrapped and sterile or be sterilized at the time of use.
 - (2) through (3)(b) remain the same.
- (c) After autoclaving, the package must be dated and initialed by the <u>body</u> artist. If the autoclaved instrument or jewelry is not used within six months of the sterilization date, or if the packaging is no longer intact, the article must be rewrapped and resterilized before use.
 - (d) remains the same.
- (e) The department or its designee may require that an operator submit the results of a monthly spore test directly to its office if the establishment fails to perform a monthly spore text test or has one or more failed spore tests.
 - (f) remains the same.
- (g) Following sterilization, equipment, and jewelry must remain in the autoclave packaging.
 - (4) remains the same.

- <u>37.112.132 CLEANING AND ULTRASONIC USE</u> (1) All nondisposable reusable instruments used for tattooing and body piercing body art procedures must be cleaned thoroughly with an appropriate soap or detergent and rinsed completely with potable water.
- (2) Each establishment Establishments that reuse instruments must have at least a one-compartment sink with hot and cold running water for the cleaning of instruments or an automated instrument washer. The sink must be used only for cleaning contaminated instruments and shall not be used for hand washing. The sink must be of an adequate size to submerge the instruments being cleaned, except as provided in (3) of this rule.
 - (3) remains the same.
- (4) An ultrasonic cleaning unit must be used in accordance with the manufacturer's instructions. An ultrasonic cleaning unit does not satisfy the sterilization requirements in ARM 37.112.131, with or without the addition of chemical sanitizers.
 - (5) remains the same.
- (6) The covered ultrasonic unit and the sink used for rinsing and scrubbing contaminated tools must be separated from the autoclave to prevent contamination. If space is an issue, the establishment may install a Plexiglas, stainless steel, or other nonporous barrier to prevent cross contamination.
 - (7) All reusable instruments must be cleaned in a separate cleaning room.
 - (a) The cleaning room must be enclosed and not open to the public.

- (b) The cleaning room must only be used for cleaning, disinfecting, sterilizing, storage, and related tasks. No other services, including tattooing, piercing, or retail sales, may occur within this sterilization room/area.
- (c) If any items are stored in the cleaning room, cabinets or drawers must be made of smooth, nonporous wipeable materials.

37.112.133 SKIN PREPARATION, ASEPTIC TECHNIQUE, AND

<u>AFTERCARE</u> (1) Aftercare instructions appropriate for the tattooing or body piercing body art procedure that describe effective means of infection prevention must be provided to the client both verbally and in writing before every procedure.

- (2) At all times during the tattooing or body piercing body art procedure, body artists must use sterile instruments as specified in ARM 37.112.131 and aseptic techniques.
- (3) Before and after performing the tattooing or body piercing body art procedure, body artists must remove all rings, watches, and bracelets, and before and after performing the body art procedure, a body artist must then thoroughly wash their hands, wrists, and lower arms in warm running water with soap for at least 20 seconds, scrubbing around and under their fingernails, rinsing completely, and drying with clean, individual, disposable towels, and use a new clean disposable towel to turn off the faucet.
- (4) Artists Body artists must wear a clean outer garment. A hair restraint must be worn if necessary to prevent the <u>body</u> artist's hair from contact with the client. All necklaces, bracelets, or other personal items of the <u>body</u> artist either must be removed or covered by the outer garment or sterile gloves to prevent the item coming in contact with the client.
- (5) If it is necessary to shave the client's skin area to be tattooed or pierced, the <u>body</u> artist must use single-use razors. Straight razors, electric razors, and replaceable blade units may not be used. After shaving the client's skin, the <u>body</u> artist must:
 - (a) wash and scrub the artist's their hands as described in (3) of this rule; and
 - (b) remains the same.
- (6) If the <u>body</u> artist wore gloves to wash or shave the client's skin, the <u>body</u> artist must discard those gloves after completing those tasks. The <u>body</u> artist must then remove gloves, wash hands, and put on a new pair of gloves before continuing the procedure.
- (7) Before performing the tattooing or piercing body art procedure, the skin and surrounding area where the procedure is to be done must be thoroughly dampened with an antiseptic using a clean single-use cotton ball, gauze, or tissue.
- (8) If it is necessary to use a marking device, the marking device will be used only once and disposed of or it must be autoclaved between uses.
- (9) New gloves must be put on before each tattooing and piercing body art procedure.

- (10) If the <u>body</u> artist's gloved hands become contaminated during the <u>tatteoing or body piercing body art</u> procedure, then the <u>body</u> artist must remove <u>the</u> gloves, wash hands, and put on a new pair of gloves before resuming the procedure.
 - (a) remains the same.
- (b) If the <u>body</u> artist sustains a needle stick, the <u>body</u> artist must resume the <u>tattooing or body piercing body art</u> procedure with clean and sterile equipment after rewashing hands and regloving. <u>If a needle stick occurs, the department</u> recommends consulting a health care provider.
 - (11) remains the same.
- (12) Upon completion of the tattooing or piercing body art procedure, body artists must apply an antiseptic solution to the procedure area in accordance with the manufacturer's instructions with a clean single-use cotton ball, gauze, or tissue. In the case of a tattoo, the artist must then apply a sterile absorbent bandage to the tattooed site. In the event of bleeding, all products used to stop the flow of blood or to absorb blood must be sterile, single-use items that are disposed of immediately after use in appropriate covered containers. All products used to cover the procedure site must be used in accordance with the manufacturer's instructions.

37.112.137 HANDLING AND DISPOSAL OF INFECTIOUS MATERIAL

- (1) through (3) remain the same.
- (4) An A body artist must use adequate protections, such as a brush, dust pan, or tongs to pick up any broken glassware in the work room. After engaging in such cleaning, the <u>body</u> artist must wash hands and reglove as described in ARM 37.112.133 before working with a client.
 - (5) and (6) remain the same.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

- 37.112.141 RECORD KEEPING AND REVIEW (1) and (1)(a) remain the same.
 - (b) typed or, printed in ink, or electronic.
- (2) Each establishment must keep on the premises current copies of the Montana Code Annotated and Administrative Rules governing tattooing and body piercing establishment, and upon request make these available for review to any artist, client, client's parent, or client's legal guardian.

- 37.112.142 CLIENT RECORD (1) and (1)(a) remain the same.
- (b) the name of the <u>body</u> artist who performed the <u>tattooing or body piercing</u> <u>body art</u> procedure;
 - (c) remains the same.

- (d) special instructions or information regarding the client's medical or skin conditions which are relevant to the tattooing or body piercing body art procedure; and
 - (e) remains the same.

- <u>37.112.144 CONSENT FORM</u> (1) The client must sign a consent form before each tattooing or body piercing body art procedure. If the client is under the age of 18, then the client's parent or legal guardian must sign the consent form, in person, before the procedure.
 - (2) remains the same.
- (a) the client's name and address, the date of the procedure, the design of the tattoo, if applicable, the location of the procedure on the client's body, and any other information that the body artist may consider appropriate;
 - (b) through (d) remain the same.
- (e) the permanent nature of either tattoos or specific piercings or both the body art procedures; and
 - (f) remains the same.
- (i) has been provided with the aftercare instructions, both in writing and verbally by the <u>body</u> artist; and
 - (ii) consents to the tattooing or body piercing body art procedure.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

- <u>37.112.147 TRAINING</u> (1) Operators and <u>body</u> artists must complete formal training in at least general sanitation, first aid, and universal precautions for preventing the transmission of blood-borne pathogens before licensure. Training may be provided by the department, its designee, or an organization approved by the department or its designee as having adequate content in each subject.
- (2) Operators and <u>body</u> artists must maintain current training certification with approved providers for first aid, and universal precautions for preventing the transmission of blood-borne pathogens and follow certifying organizations guidelines for expiration and renewal.
- (3) Guest <u>body</u> artists and new <u>body</u> artists must complete formal training and provide the inspecting authority with documentation of this training prior to working in a licensed facility.
 - (4) and (5) remain the same.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

<u>37.112.151 LICENSE APPLICATION</u> (1) remains the same.

(2) The applicant <u>for licensure</u> <u>of license</u> and all <u>body</u> artists working in the proposed establishment shall be at least 18 years of age at the time of application.

- (3) and (4) remain the same.
- (5) Obtaining a license from the department does not relieve the applicant from satisfying applicable requirements from other federal, state, or local agencies. These requirements may include, but are not limited to:
 - (a) through (c) remain the same.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-201, MCA

- <u>37.112.152 LICENSE FEE AND EXPIRATION</u> (1) Except as provided in (2), the license fee is \$135 \$185 each for a tattoo license and body piercing license.
 - (2) The license fee for establishments that only pierce ear lobes is \$75 \$125.

(3) remains the same.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-201, MCA

- 37.112.156 REVIEW OF PLANS (1) remains the same.
- (2) For initial plan reviews submitted to the department, the initial plan review fee is \$200 and must be submitted by the applicant before the plan review will begin.
 - (2) and (3) remain the same but are renumbered (3) and (4).
- (4)(5) If the facility was previously licensed or certified by the department as a tattooing or body piercing body art establishment and no structural modification is involved, the department may waive the requirement for the submission of plans.
 - (5) remains the same but is renumbered (6).

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

- <u>37.112.157 INSPECTION</u> (1) and (2) remain the same.
- (3) Whenever an inspection of an establishment is made, the department or its designee will document its findings on an inspection form. A copy of the completed inspection report form will be given to the person in charge of the establishment within ten days of the inspection. At the conclusion of the inspection, the department or its designee shall provide a copy of the completed inspection report and the notice to correct violations to the person in charge of the establishment and request a signed acknowledgment of receipt.
 - (a) through (c) remain the same.

AUTH: 50-48-103, MCA

IMP: 50-48-103, 50-48-206, MCA

- <u>37.112.158 RESTRICTIONS AND PROHIBITIONS</u> (1) A tattooing or body piercing body art procedure may not occur if:
- (a) either the <u>body</u> artist or the client is under the apparent influence of alcohol or other mind-altering drugs;
 - (b) through (2) remain the same.

- (3) A written physician referral is required before tattooing or body piercing <u>a</u> body art procedure if the client:
 - (a) through (e) remain the same.
- (4) The <u>body</u> artist may delay or require a medical referral before conducting any tattooing or piercing <u>body</u> art <u>procedure</u> for any person whose physical health, understanding, or judgment may be in question.

<u>37.112.163 TATTOOING: COLORS, DYES, AND PIGMENTS</u> (1) remains the same.

- (2) Pigments mixed or prepared in the tattoo establishment must be prepared and stored in accordance with the manufacturer's instructions. When using water to mix colors, dyes, and pigments, distilled or sterilized water must be used.
- (3) A tattooist who becomes aware of a client who has experienced an apparent reaction, allergy, or sensitivity to a pigment used in tattooing must report the condition and pigment information to the Department of Public Health and Human Services, Public Health and Safety Division, Food and Consumer Environmental Health and Food Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951 or the local health officer.
- (4) Adulterated pigments or those containing deleterious substances may be subject to voluntary hold, manufacturer recall, or other action under the Montana Food, Drug and Cosmetic Act, Title 50, chapter 31, MCA; the Federal Food, Drug and Cosmetic Act; or other federal, state, or local law.
 - (4) through (6) remain the same but are renumbered (5) through (7).

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

<u>37.112.165 BODY PIERCING: ADDITIONAL REQUIREMENTS AND RESTRICTIONS</u> (1) remains the same.

- (2) Piercing guns may be used on the ear lobe only and shall not be used on body parts such as cartilage, nostrils, navels, eyebrows, and tongues.
 - (2) and (2)(a) remain the same but are renumbered (3) and (3)(a).
- (b) the practice of a physician or licensed medical professional as long as the person does not hold himself or herself out as a body piercer artist;
 - (c) the practice of acupuncture; and
- (d) other types of body modifications, including but not limited to cutting muscle to make a permanent split such as tongue-splitting, cutting into bone, trepanation (drilling into the skull), dental modification, amputation, implants, saline injection, vacuum pumping, circumcision, castration, penectomy, and subincision or superincision of genitals.

37.112.167 BODY PIERCING: EAR LOBE PIERCING EXEMPTIONS

- (1) Establishments that perform ear lobe piercing only by using a mechanized presterilized ear-piercing system gun approved by the department or its designee may be exempted from ARM 37.112.116(2), and 37.112.117(2), (5), and (8) as long as if:
- (a) the work area in which ear lobe piercing takes place is separated enough from the other areas so that no physical contact can be reasonably expected to occur between the general public and the client or artist;
- (b) a minimum of 30 foot-candles of light is provided at the level where the ear piercing is being performed. Spot lighting may be used to achieve this degree of illumination; and
- (e) the <u>body</u> artist and client <u>must</u> have convenient access to handwashing facilities <u>sinks</u>. If the handwashing facility <u>sink</u> is not within the work room or within ten feet of the work room door, then a 70% alcohol-based hand sanitizer must be used in accordance with the U.S. Centers for Disease Control "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16) immediately before putting on gloves and immediately after removal of the gloves. The department adopts and incorporates, by reference, the U.S. Centers for Disease Control "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, 2002, Vol. 51, No. RR-16). Copies of this guideline may be obtained by contacting the <u>Montana</u> Department of Public Health and Human Services, Public Health and Safety Division, Food and Consumer Environmental Health and Food Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: 50-48-103, MCA IMP: 50-48-103, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) proposes this rulemaking to update, consolidate, simplify, and make more user-friendly the administrative rules governing body art. These rules have not been updated since 2013.

The proposed rule changes are necessary to ensure continued public health and safety and to address new trends in body art such as the practice of scarification and branding. The proposed rule changes implement nationally recognized health and safety standards for body art and are based in part on the Body Art Model Code published by the National Environmental Health Association.

Technical, stylistic, and nonsubstantive updates are also proposed to make the rules clearer and more user-friendly.

NEW RULE I

The department is proposing NEW RULE I to establish clear standards for jewelry used for initial body piercings and to create record keeping requirements to ensure

compliance with the standards. Jewelry inserted by a body artist following an initial piercing is worn inside an open wound. As it is in contact with an individual's internal tissues, jewelry must be biocompatible to avoid adverse reactions such as contact dermatitis, scar tissue, infection, and other issues that might arise with the use of substandard jewelry. The proposed rule is intended to ensure biocompatible jewelry is used to help ensure there are no adverse health effects to the client.

NEW RULE II

The department is proposing NEW RULE II to establish health and safety standards for branding. The rule requires the body artist and client to wear protective face masks rated as N95 or higher, as the fumes produced from branding when flesh burns can be toxic and potentially spread disease and infection. To protect against any harmful airborne byproducts and reduce the spread of airborne pathogens, the rule also requires the work room where branding occurs to be enclosed and have an appropriately sized ultraviolet air purifier. The rule also sets forth nationally recognized best practices to ensure branding is safely conducted.

NEW RULE III

The department is proposing NEW RULE III to establish health and safety standards for scarification. Scarification generally involves cutting into the skin and mucus membranes, which can increase the risk of exposure to and infection with bloodborne pathogens, such as hepatitis B, hepatitis C, and HIV. The rule requires the use of personal protective equipment to decrease the risk of exposure to infectious diseases. To protect against any harmful airborne byproducts and reduce the spread of airborne pathogens, the rule requires the work room where the scarification procedure is performed to be enclosed and have an appropriately sized ultraviolet air purifier.

ARM 37.112.102

The department proposes to revise this rule to update terminology and increase clarity of the rule.

ARM 37.112.103

The department proposes to amend this rule to clarify the meaning of terms used throughout the body art rules and to provide for a better understanding of these rules. Definitions of terms defined in statute have been removed from this rule. The department has also updated the rule to use terminology that is consistent with current law and nationally recognized health and safety standards.

ARM 37.112.108

The rule currently prohibits body art procedures from being performed in any living or sleeping area. The department is proposing to amend this rule to clarify that this prohibition extends to such areas with bathrooms or handwashing sinks and that client access to a body art establishment must be separate from access to a living or sleeping area.

ARM 37.112.116

The department proposes to amend this rule to allow for the use of non-disposable single-use towels in toilet and handwashing rooms provided they are properly laundered after each use. Technical and stylistic changes are also proposed to improve the clarity of the rule.

ARM 37.112.117

The department proposes to amend this rule to clarify and update health and safety requirements for work rooms where body art procedures are performed in accordance with nationally recognized best practices.

ARM 37.112.121

The department proposes to amend this rule to clarify and update health and safety requirements for temporary and mobile establishments where body art procedures are performed in accordance with nationally recognized best practices.

ARM 37.112.125

The department proposes to amend this rule to clarify and update health and safety requirements pertaining to equipment and supplies used for body art procedures in accordance with nationally recognized best practices.

ARM 37.112.129

The department proposes to amend this rule to clarify the version of the federal regulation that is adopted and incorporated by reference in the rule.

ARM 37.112.131

The department proposes to amend this rule to allow body art establishments to sterilize equipment at the time of use, which will save time and supplies for the establishment while still ensuring public health and safety.

ARM 37.112.132

The department proposes to amend this rule to allow automated washers and require a sink only if instruments are reused. The department is also proposing amendments to update health and safety requirements pertaining to the cleaning and storage of reusable instruments that are used in body art procedures.

ARM 37.112.133

In response to stakeholder feedback, the department is proposing to amend this rule to remove language requiring tattoos to be covered by absorbent bandages. The proposed rule change allows for the use of non-absorbent bandages such as Saniderm. Technical and stylistic changes are also proposed to improve the clarity of the rule.

ARM 37.112.137, 37.112.141, 37.112.142, 37.112.144, 37.112.147, and 37.112.151 Technical, stylistic changes and updates to terminology are proposed to improve the clarity of these rules.

ARM 37.112.152

The department proposes to amend this rule to increase license fees to help offset the cost to taxpayers associated with licensure and oversight of body art establishments by the department. The fees in this rule have not been changed since 2013 and do not cover the actual cost associated with licensure and oversight performed by the department.

ARM 37.112.156

The department proposes to amend this rule to establish plan review fee of \$200 to cover the cost of the average amount of time spent by department staff for each plan review. The amount of the fee is consistent with fees local health departments charge for plan reviews.

ARM 37.112.157

The department proposes to amend this rule to clarify the process of providing an inspection report to a body art establishment following completion of an inspection by the department or local health authority.

ARM 37.112.158

Technical and stylistic changes and updates to terminology are proposed to improve the clarity of these rules.

ARM 37.112.163

The department proposes to amend this rule to clarify that water must be distilled or sterilized when used to mix colors, dyes, or pigments for tattooing.

ARM 37.112.165

The department proposes to amend this rule to clarify ear piercing guns may be used on the ear lobe only. Ear piercing guns cannot be sanitized in a medically recognized way. Plastic ear-piercing guns cannot be autoclave sterilized and may not be sufficiently cleaned between use on multiple clients. Even if antiseptic wipes used were able to kill all pathogens on contact, simply wiping the external surfaces of the gun with an antiseptic does not kill pathogens within the working parts of the gun, which cannot be taken apart. Ear piercing studs used in the guns are too short for most cartilage. Pressure of such tight jewelry can result in additional swelling and infection because it does not allow for thorough cleaning.

ARM 37.112.167

This rule currently exempts body art establishments that perform only ear lobe piercing procedures from having to meet work room barrier requirements under ARM 37.112.117(2) and lighting requirements under ARM 37.112.117(5). The department proposes to amend this rule to remove these exemptions from compliance with the barrier and lighting requirements. This is to ensure public health and safety by requiring adequate lighting in the work room and separation from the public as well as any contaminated surfaces. This proposed rule change applies only to newly licensed establishments and current establishments who remodel or change location.

Fiscal Impact

Two rule changes associated with this rulemaking have a fiscal impact: (1) the proposed fee increases for licensure under ARM 37.112.152; and (2) establishment of a plan review fee under ARM 37.112.156.

Fee increases for licensure under ARM 37.112.152

This proposed rule amendment will result in the department collecting an estimated \$14,000 per year in license fees, of which \$12,600 will be available for county health departments to collect for conducting inspections. The proposed fee is estimated to affect 270 body art establishment owners.

Establishment of a plan review fee under ARM 37.112.156

This proposed rule amendment will result in the department collecting an estimated \$6,000 per year in plan review fees. The proposed amendment will affect new establishments applying for a license and existing establishments who change location or complete a significant remodel. The proposed amendment is estimated to affect 30 body art establishments per year.

- 5. 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: Bailey Yuhas, 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 hhsadminrules@mt.gov, and must be received no later than 5:00 p.m., January 17, 2025.
- 6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.
- 7. 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. Written requests may be mailed or delivered to the contact person in 5 above.
- 8. An electronic copy of this notice is available on the department's web site at https://dphhs.mt.gov/LegalResources/administrativerules, or through the Secretary of State's web site at rules.mt.gov.
 - 9. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.
- 10. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption and amendment of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Robert Lishman/s/ Charles T. BreretonRobert LishmanCharles T. Brereton, DirectorRule ReviewerDepartment of Public Health and Human

Services

Certified to the Secretary of State December 10, 2024.