



MONTANA
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REGISTER



DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

NOTICE OF ADOPTION

MAR NOTICE NO. 37-1072

Summary

Adoption of NEW RULES I through III and 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 Tattooing

Previous Notice(s) and Hearing Information

On December 20, 2024, the Department of Public Health and Human Services published MAR Notice No. 37-1072 pertaining to the public hearing on the proposed adoption and amendment of the above-stated rules at page 2584 of the 2024 Montana Administrative Register, Issue Number 24.

The public hearing was held on January 9, 2025.

Final Rulemaking Action – Effective April 26, 2025

ADOPT AS PROPOSED

The agency has adopted the following rules as proposed:

NEW RULE I (37.112.164) JEWELRY STANDARDS FOR INITIAL BODY PIERCINGS

NEW RULE II (37.112.160) BRANDING SAFETY AND SANITATION REQUIREMENTS

NEW RULE III (37.112.161) SCARIFICATION SAFETY AND SAFETY REQUIREMENTS

AMEND AS PROPOSED

The agency has amended the following rules as proposed:

37.112.102 PURPOSE

37.112.108 GENERAL FACILITY REQUIREMENTS

37.112.116 TOILETS AND HANDWASHING SINKS

37.112.125 EQUIPMENT AND SUPPLIES

37.112.129 BLOOD-BORNE PATHOGEN EXPOSURE CONTROL

37.112.131 STERILIZATION OF EQUIPMENT AND JEWELRY

37.112.137 HANDLING AND DISPOSAL OF INFECTIOUS MATERIAL

37.112.141 RECORD KEEPING AND REVIEW

37.112.142 CLIENT RECORD

37.112.144 CONSENT FORM

37.112.147 TRAINING

37.112.151 LICENSE APPLICATION

37.112.152 LICENSE FEE AND EXPIRATION

37.112.157 INSPECTION

37.112.158 RESTRICTIONS AND PROHIBITIONS

37.112.163 TATTOOING: COLORS, DYES, AND PIGMENTS

37.112.167 BODY PIERCING: EAR LOBE PIERCING EXEMPTIONS

AMEND WITH CHANGES

The department has amended the following rules with the following changes from the original proposal, stricken matter interlined, new matter underlined:

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 body art procedure.
- (2) "Antiseptic" means a 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) "Aseptic technique" means a procedure that prevents contamination of any object or person.
- (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~~ a person performing body art services.
- (9) "Body modification" is the intentional altering of the human body for any nonmedical reason.
- (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.
- (11) "Cleaning room" means the room used to sterilize instruments and jewelry with an autoclave.
- (12) "Client" means an individual on whom a body artist performs a body art procedure.
- (13) "Contaminated" means the probable presence of blood or other potentially infectious materials on an item or surface.
- (14) "Disinfectant" means a substance or solution, registered with the United States Environmental Protection Agency (EPA), which kills or inactivates viruses and pathogenic microorganisms, but not necessarily their spores.

- (15) "Ear lobe piercing" means the puncturing of the ear lobe, but not the ear cartilage, to create a permanent hole for cosmetic purposes.
- (16) "Easily cleanable" means a characteristic of a surface that allows effective removal of soil by normal cleaning methods.
- (17) "Equipment" means all machinery, including fixtures, containers, vessels, instruments, tools, devices, implements, furniture, display and storage areas, sinks, and all other apparatus and appurtenances used in connection with the operation of an establishment.
- (18) "Implant" means any transdermal or subdermal object that is embedded into a person's body. Implants do not include microdermal anchors or two-point piercings.
- (19) "Infectious waste" has the meaning provided for in 75-10-1003, MCA.
- (20) "Ink cup" means a small container for an individual portion of pigment which may be installed in a holder or palette, and in which a small amount of pigment is placed.
- (21) "Instrument" means a 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 body art procedure.
- (22) "Jewelry" means any 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.
- (24) "Microdermal anchor" means a piece of jewelry used for single-point piercings that has a foot no larger than 8mm in length.
- (25) "Mobile establishment" means a licensed facility where body art is conducted, utilizing a wheeled vehicle for movement from place to place.
- (26) "Operator" means any owner of an establishment or any person who is responsible for the establishment as well as the other body artists working at the establishment, for the purpose of meeting the requirements of this chapter.
- (27) "Permanent cosmetics" means 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.

- (28) "Physician" means a person licensed to practice medicine in Montana by the Montana Board of Medical Examiners under the Department of Labor and Industry.
- (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.
- (30) "Sanitization" means the effective treatment of surfaces of inanimate objects by a product registered by the EPA that provides a sufficient concentration of chemicals and enough time to reduce the bacterial count, including pathogens, to a safe level.
- (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.
- (32) "Sharps" means any discarded instrument or article that may be contaminated with blood or other bodily fluid and may cause punctures or cuts, including needles, scalpel blades, uncovered razors, and broken glass. A disposable shaving razor with protective cap in place is not considered a sharp.
- (33) "Single-point piercing" means a piercing that creates a hole in the skin that acts as both the entry and exit for a microdermal or transdermal anchor.
- (34) "Single-use" means 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.
- (35) "Sterilize" means to treat an object or surface with a procedure that kills or irreversibly inactivates all microorganisms, including bacteria, viruses, and pathogenic fungi, including their spores.
- (36) "Strike branding" means the process by which a mark is burned with heated metal into the tissue of a person.
- (37) "Subdermal object" means an item that is implanted under the skin.
- (38) "Tattooist" means a person who engages in the practice of tattooing.
- (39) "Temporary establishment" means a facility where body art is conducted for not more than 14 days at one location in a calendar year.
- (40) "Transdermal anchor" means a piece of jewelry used for single-point piercings that has a foot larger than 8mm in length.
- (41) "Transdermal object" means an item that is passed, entered, or made by penetration through the skin. Transdermal objects do not include microdermal anchors.
- (42) "Two-point piercing" means a piercing that punctures the skin creating a distinct entry and exit point.

- (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.
- (44) "Universal precautions" means the current set of guidelines and controls published by the U.S. Centers for Disease Control and Prevention that includes specific recommendations for the use of protective equipment such as gloves, masks, or protective eye wear whenever contact with blood or body fluids containing blood is anticipated.
- (45) "Work room" means a designated room or area in which 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.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-102, 50-48-103, MCA

37.112.117 WORK ROOM REQUIREMENTS

- (1) All body art procedures must take place in the work room only.
- (2) The work room must be separated by a barrier from the waiting area. The room does not need to have complete physical separation, but it must be segregated by counters, self-closing doors, or other barriers so that clients or other employees may not enter the work room unless they open the barrier to gain access.
- (3) The work room may not be used as a corridor for access to other rooms.
- (4) Animals are not allowed in the establishment work room, except for:
 - (a) patrol dogs accompanying security or ~~police officers~~ law enforcement;
 - (b) ~~and~~ service animals such as guide dogs; and;
 - (c) aquatic species within ~~Fish aquariums are allowed located~~ in waiting rooms and areas outside of the work room provided that the aquatic species can survive underwater for a minimum of 48 hours. ~~Fish aquariums may contain only aquatic species that can survive underwater for a minimum of 48 hours.~~
- (5) The work room must have a minimum of 50 foot-candles of light measured at the level where the procedure is implemented. Spot lighting may be used to achieve this degree of illumination.

- (6) The work room must have adequate ventilation.
- (7) Openings to the outside must be protected by such means as self-closing doors, screened or closed windows, or air currents to protect against the entrance of insects, rodents, or other animals. Screening material must not be less than 16 mesh to the inch.
- (8) Work rooms must have at least one handwashing sink unless there is a handwashing 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.
 - (b) If the handwashing sink is outside the work room, the work room door must ~~be have~~ a two-way self-closing door. The two-way self-closing door may be a solid door, swinging café door, or curtain.
 - (c) The handwashing sink cannot be in the same room as the toilet.
 - (d) If controls for wrist or foot activation are not available, single service towels must be used for turning controls off after washing hands.
 - (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.
 - (f) The handwashing sink must be provided with hot and cold running water by means of a mixing valve or combination faucet, except as provided in ARM 37.112.121(2) regarding temporary or mobile establishments.
 - (g) Any self-dispensing, slow-closing, or metering faucet used must be designed to provide a flow of water for at least 20 seconds without the need to reactivate the faucet.
 - (h) Steam mixing valves are prohibited.
 - (i) Soap must be conveniently located near the handwashing sink.
 - (j) Individual, disposable towels must be conveniently located for drying hands.
- (9) The work room must have a sufficient number of waste receptacles for the disposal of waste materials.
 - (a) Waste receptacles must be lined and covered. The receptacles must be cleanable, kept clean, and have self-closing lids with hands-free controls.
 - (b) Waste receptacles in the work room must be emptied daily or more often, as needed.

- (c) A dedicated container for the disposal of sharps and a dedicated container for other contaminated waste must be located in the work room in accordance with ARM 37.112.137 for disposal of infectious material.
- (10) The work room must be maintained in a clean condition.
- (11) The floor of the work room must be constructed of smooth and impervious materials that are easily cleanable and in good condition. The floor must be wet-mopped daily.
- (12) Except as provided in (12)(a), tobacco use, vaping, eating, or and drinking is are prohibited in the work room, except where body art preparations and procedures are performed and any location where instruments or supplies are stored or cleaned.
 - (a) Eating and drinking is allowed when needed for first aid purposes. The use of bottled water and covered drinks is allowed. Hands must be washed and body artists must use a new pair of gloves before returning to the procedure area.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-103, MCA

37.112.121 TEMPORARY OR MOBILE ESTABLISHMENT

- (1) A temporary or mobile establishment may be operated if:
 - (a) the operator submits to the department or its designee a written plan that demonstrates how the temporary or mobile establishment will meet the provisions of these rules, or will use alternatives that provide equivalent protection as provided by these rules; and
 - (b) the department or its designee issues written approval of the plan.
- (2) A temporary or mobile establishment that cannot provide mechanically heated water may provide temperate water for hand washing as long as the water is provided in a system that is constructed and operated in accordance with applicable state and local laws for potable water.
- (3) A temporary or mobile establishment that cannot meet ARM 37.112.115(1) regarding sewage systems may use an acceptable portable toilet unit with final waste disposal that complies with applicable state and local laws.

- (4) Mobile establishments, such as a trailer, mobile home, or mobile vehicle, must have four solid walls. Outdoor tents are prohibited.
- (5) Mobile establishments must be equipped with a gravity or pressurized water storage tank. The water storage tank, or tanks, shall be sufficient capacity to meet the peak water demands of the body art establishment.
 - (a) Mobile establishments using disposable equipment only must have a water storage tank, or tanks, with a capacity of at least 38 liters (10 gallons) for handwashing.
 - (b) Mobile establishments that reuse equipment must have a water storage tank, or tanks, with a capacity of at least 151 liters (40 gallons) for handwashing, equipment washing, and sanitizing purposes.
- ~~(5)~~(6) 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)~~(7) Temporary or mobile establishments must be used solely for the purpose of body art procedures. Food prep and habitation are prohibited.
- ~~(7)~~(8) ~~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.~~ Mobile and temporary establishments must properly sterilize instruments and provide evidence of a spore test performed on sterilization equipment no later than 30 days prior to the date of the event. Otherwise only single-use, prepackaged, sterilized instruments marked with an expiration date, lot number, and method of sterilization can be used. A clean room is required if equipment is reusable, cleaned and sanitized.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-103, MCA

37.112.132 CLEANING AND ULTRASONIC USE

- (1) All reusable instruments used for body art procedures must be cleaned thoroughly with an appropriate soap or detergent and rinsed completely with potable water.
- (2) 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).

- (3) Establishments that use ultrasonic units with heating elements to clean their instruments are not required to have hot water at the cleaning sink, provided the heating elements can heat the cleaning solution and maintain the temperature according to the manufacturer's specifications.
- (4) An ultrasonic unit must be used in accordance with the manufacturer's instructions. An ultrasonic unit does not satisfy the sterilization requirements in ARM 37.112.131, with or without the addition of chemical sanitizers.
- (5) Ultrasonic unit use, cleaning, dusting, or vacuuming is prohibited during times when clients are being tattooed or pierced.
- (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) Except as provided in (8), All reusable instruments must be cleaned in a separate cleaning room.
 - (a) The cleaning room must be enclosed by four solid walls except for windows and doors 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.
- (8) Reusable tattoo machines and ear-piercing guns must be cleaned in accordance with manufacturer instructions and guidelines.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-103, MCA

37.112.133 SKIN PREPARATION, ASEPTIC TECHNIQUE, AND AFTERCARE

- (1) Aftercare instructions appropriate for the 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 body art procedure, body artists must use sterile instruments as specified in ARM 37.112.131 and aseptic techniques.
- (3) Before performing the 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 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, drying with clean, individual, disposable towels, and use a new clean disposable towel to turn off the faucet.
- (4) Body artists must wear a clean outer garment. A hair restraint must be worn if necessary to prevent the body artist's hair from contact with the client. All necklaces, bracelets, or other personal items of the body artist that could come in contact with the client must be removed ~~to prevent the item coming in contact with the client.~~
- (5) If it is necessary to shave the client's skin, the body 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 body artist must:
 - (a) wash and scrub their hands as described in (3); and
 - (b) wash and rinse the client's area of skin that was shaved.
- (6) ~~If the A body artist wore must wear gloves when to washing or shaving shave the client's skin. Following washing or shaving of the client's skin, the body artist must discard those gloves after completing those tasks. The body artist must then~~ remove the gloves, wash hands, and put on a new pair of gloves before continuing the body art procedure.
- (7) Before performing the 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.
- (9) New gloves must be put on before each body art procedure.
- (10) If the body artist's gloved hands become contaminated during the body art procedure, then the body artist must remove the gloves, wash hands, and put on a new pair of gloves before resuming the procedure.
 - (a) Inadvertent contamination of gloved hands may include touching eyes, nose or mouth, answering the phone, opening a door, or retrieving an item from the floor.
 - (b) If the body artist sustains a needle stick, the body artist must resume the body art procedure with clean and sterile equipment after rewashing hands

and regloving. If a needle stick occurs, the department recommends consulting a health care provider.

~~(11) In the event of blood flow, all materials used to stop the flow of blood or to absorb blood must be sterile and single-use.~~

~~(12)~~(11) Upon completion of the 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 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.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-103, MCA

37.112.156 REVIEW OF PLANS

- (1) Whenever an initial license is applied for, the license applicant must submit properly prepared plans and specifications to the department or its designee for review and approval before construction, remodeling, or conversion begins.
- (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. A local board of health may establish its own fee for plans that are submitted to the local health authority for review.
- (3) The plans and specifications must demonstrate how the establishment will meet the requirements of this rule, including the following:
 - (a) a layout of work rooms, waiting areas, auxiliary rooms, toilet rooms, handwashing facilities, doorways, stairways, fixed equipment, and facilities;
 - (b) specifications for any autoclave that may be used, including manufacturer and model number;
 - (c) copies of the client consent form and client record form; and
 - (d) copies of formal training documentation as described in ARM 37.112.147.
- (4) If the department or its designee disapproves of the plans, the department or its designee will make the deficiencies known to the applicant.

- (5) If the facility was previously licensed or certified by the department as a body art establishment and no structural modification is involved, the department may waive the requirement for the submission of plans.
- (6) Changes in the client consent form and client record form must be submitted to the department or its designee before implementation.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-103, MCA

37.112.165 BODY PIERCING: ADDITIONAL REQUIREMENTS AND RESTRICTIONS

- (1) If the client is under the age of three, the client's parent or legal guardian must be given verbal and written warning of the inherent choking hazard of the jewelry before the body piercing. This warning may be included on the consent form.
- (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.
- (3) For the purposes of this chapter, body piercing does not include the following:
 - (a) the practice of electrology as defined in ~~ARM Title 37, chapter 31, subchapter 4~~ 37-31-101, MCA;
 - (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 artist;
 - (c) the practice of acupuncture;
 - (d) other types of body modifications, including 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.

Authorizing statute(s): 50-48-103, MCA

Implementing statute(s): 50-48-103, MCA

Correction of Clerical Error

During internal review following the end of the public comment period, a clerical error was discovered in the current rule text under ARM 37.112.165(2)(a), adopted as (3)(a). The rule provides that body piercing does not include the practice of electrology “as defined in ARM Title 37, chapter 31, subchapter 1.” The reference to ARM Title 37, chapter 31, subchapter 1 is incorrect in that these referenced rules are unrelated to electrology. Electrology is defined under 37-31-101, MCA. The department has amended the rule to reference the statutory definition of electrology.

Statement of Reasons

The department has considered the comments and testimony received. A summary of the comments and/or testimony received, and the agency’s responses are as follows:

COMMENT #1: A commenter expressed support for the proposed rule changes.

RESPONSE #1: The department thanks the commenter for their support of the proposed rule changes

COMMENT #2: A commenter asked the following questions concerning the proposed rules:

- a. What body art establishments are licensed solely by local boards of health as referenced in ARM 37.112.102?
- b. Does ARM 37.112.117(9)(a) require that waste receptacles be under hands free control and no longer allow them to remain open during tattooing?
- c. Does ARM 37.112.133(4) require body artists to remove of all jewelry and personal items or just personal items and jewelry that could come into contact with the client?
- d. Does ARM 37.112.133(12) allow the use of bandages that are absorbent, but not sterile?

The commenter also suggested ARM 37.112.133(6) be revised to make clear whether the use of gloves is optional or required when a body artist washes or shaves the client’s skin.

RESPONSE #2: Under 50-48-203, MCA, a local board of health may implement its own licensure and regulatory program for tattooing and body-piercing establishments. If the local board of health implements such a program, the requirements cannot be less stringent than those set forth in the department’s body art rules and the program operates in lieu of the department's licensure and regulatory program. ARM 37.112.117(9)(a) requires that waste receptacles in the

workroom have self-closing lids with hands-free control so they are not open during body art procedures. ARM 37.112.133(4) is intended to require the body artist remove only jewelry and other personal items that could come into contact with the client. The department has revised the rule for clarity. ARM 37.112.133(11) requires that all products, including bandages, applied in the event of bleeding be sterile. The department has revised ARM 37.112.133(6) to clarify that gloves must be used if the body artist is shaving or washing the client's skin.

COMMENT #3: A commenter sought clarification on whether ARM 37.112.133(6) is intended to make the use of gloves optional or required when a body artist washes or shaves the client's skin.

RESPONSE # 3: Please see the response to comment #2.

COMMENT #4: A commenter sought clarification of whether the initial plan review fee under ARM 37.112.156(2) of \$200 for plan reviews submitted to the department also applies to plan reviews completed by a local board of health or whether local boards of health may continue to set the amount of the fee charged for plan reviews performed by a local health authority. The commenter noted that ARM 37.112.103 removes the definition of the term "department."

RESPONSE #4: The definition of "department" was removed from ARM 37.112.103 because the term is statutorily defined under 50-48-102, MCA. The rule as revised incorporates this statutory definition and the reference to "department" in ARM 37.112.156 means the Department of Public Health and Human Services. The \$200 plan review fee applies only to plan reviews submitted to the department. A local board of health may continue to set the amount of the fee, if any, they wish to charge for plan reviews performed by the local health authority. The department has revised the rule for clarity.

COMMENT #5: A commenter asked whether the \$200 fee for plan reviews submitted to the department allows local boards of health to charge a lesser amount for plan reviews submitted to them.

RESPONSE #5: Please see the response to comment #4.

COMMENT #6: A commenter sought clarification as to what contamination means under ARM 37.112.133(10).

RESPONSE #6: ARM 37.112.133(10)(a) provides that inadvertent contamination of gloved hands includes "touching eyes, nose or mouth, answering the phone, opening a door, or retrieving an item from the floor."

COMMENT #7: A commenter indicated the rules should be revised to provide for definitive separation between permanent cosmetics and tattooing.

RESPONSE #7: The department disagrees and believes that permanent cosmetics is a type of tattooing given the definition of tattooing under 50-48-102, MCA, which provides that “tattooing” means “making permanent marks on the skin of a live human being by puncturing the skin and inserting indelible colors. The term includes imparting permanent makeup on the skin such as a permanent lip coloring and permanent eyeliner.”

COMMENT #8: A commenter requested clarification as to the standards for hand washing and hand sanitizing under ARM 37.112.167.

RESPONSE #8: ARM 37.112.167 applies to establishments that perform ear lobe piercing through the use of an approved piercing gun only. The rule allows these types of establishments to use a 70% alcohol-based hand sanitizer in accordance with CDC guidelines if a handwashing sink is not in the workroom or within 10 feet of the workroom. All other body art establishments are required to have a handwashing sink within the work room or within 10 feet of the work room door. ARM 37.112.117(8).

COMMENT #9: A commenter expressed concern that ARM 37.112.117 does not allow for covered drinks or water bottles in the workroom and indicated their practice is to provide clients with bottled water to ensure they remain hydrated during procedures. The commenter requested the rule be revised to allowed covered drinks in workrooms outside of the immediate work area provided that the body artist take off their gloves and washes their hands prior to handling any drink. The commenter also asked whether reporting under ARM 37.112.163 to the department of adverse client reactions is required to be made on a standard form or a form created by the establishment. The commenter also asked how long they would have to replace cabinets within a workroom that do not meet the requirement to be nonporous.

RESPONSE #9: The department has revised ARM 37.112.117(12) for clarity. There is not a standard form prescribed by the department to report adverse client reactions, and the establishment may use their own form to satisfy the reporting requirement. If the establishment has a clean room with cabinets, they are required to be of nonporous material and would need to be replaced if not so constructed. The establishment would need to work with county health department on the timeline for replacement.

COMMENT #10: A commenter inquired into the reason the rules are being revised and who requested the rule changes. The commenter questioned the need for the fee increase under ARM 37.112.152 and why fees are broken out separately for tattoo and body piercing licenses. The commenter expressed concern that questions asked during the hearing were not answered. The commenter also questioned what will be permitted with respect to scarification under NEW RULE III.

RESPONSE #10: The statement of reasonable necessity explains the department’s reasoning for amending the rules, how the rule changes were developed, and the basis for the proposed increase in fees. Under the existing rules, there are three license types: tattooing, body

piercing, and ear lobe only piercing. No changes to these categories of licensure are being proposed as part of this rulemaking. Consistent with the requirements of the Montana Administrative Procedure Act, the department has responded through this adoption notice to the comments and questions presented during hearing. The term “scarification” used in NEW RULE III (ARM 37.112.161) is defined under ARM 37.112.103 and is limited to processes under which a mark or marks are cut into human skin tissue with the intention of leaving a permanent mark. ARM 37.112.165(2)(d) specifically excludes, as body piercing, procedures that involve cutting muscle to make a permanent split such as tongue-splitting.

COMMENT #11: A commenter suggested revising the definition of “body artist” in ARM 37.112.103 to remove language requiring the artist to be age 18 or older. The commenter noted the language is redundant to ARM 37.112.151(2).

RESPONSE #11: The department agrees and has revised the rule accordingly.

COMMENT #12: A commenter suggested revising ARM 37.112.117 to clarify whether allowing fish aquariums in waiting areas means all other animals other than fish are prohibited in waiting areas.

RESPONSE #12: The department has revised the rule for clarity.

COMMENT #13: A commenter suggested revising ARM 37.112.121 to establish specific water and wastewater requirements for mobile establishments to ensure these types of establishments have sufficient tank storage to protect public health.

RESPONSE #13: The department agrees with the suggestion and has revised the rule accordingly to add wastewater requirements that are modeled after the department’s mobile establishment retail food rule.

COMMENT #14: A commenter suggested that language under ARM 37.112.121 prohibiting temporary and mobile establishments from using autoclaves be removed. The commenter indicates these types of establishments can appropriately be outfitted with an autoclave and notes that prohibiting autoclaves is inconsistent with other rule language.

RESPONSE #14: The department agrees and has revised the rule accordingly.

COMMENT #15: A commenter suggested revising ARM 37.112.132(6) to use the term “automated instrument washer” instead of “ultrasonic unit” since not all automated washers are ultrasonic.

RESPONSE #15: The department disagrees. Ultrasonic units and automated washers are different pieces of equipment and are separately defined in ARM 37.112.103.

COMMENT #16: A commenter suggested revising ARM 37.112.132(7) to clarify if the cleaning room must be on the premises of the establishment or can be in a remote location. The commenter also requested clarification on whether tattoo machines and ear-piercing guns are considered “reusable instruments” under the rule.

RESPONSE #16: The department believes the rule makes clear that the cleaning room must be on the premises of the establishment given the requirement under ARM 37.112.132(2) for establishments that reuse instruments to have a one compartment sink or an automated instrument washer. The department has revised the rule to clarify requirements for the cleaning of tattoo machines and ear-piercing guns.

COMMENT #17: A commenter suggested revising ARM 37.112.132(7)(a) to clarify the meaning of the term “enclosed.”

RESPONSE #17: The department has revised the rule for clarity.

COMMENT #18: A commenter noted that the proposed revision to ARM 37.112.133(12) contains language that is redundant to language under (11). The commenter also suggested that ARM 37.112.133(11) be revised to add a requirement for disposing of sterile products into a covered container.

RESPONSE #18: The department has revised the rule to remove the redundant language. The requirement to dispose of sterile products into closed containers was proposed in the proposed amendment to ARM 37.112.133(12), which has been adopted as final in ARM 37.112.133(11).

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Approval

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