

RULE 37.112.102 PURPOSE (1) The rules in this chapter pertain to tattooing and body piercing 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 establishments that are licensed solely by local boards of health pursuant to 50-48-203, MCA.

RULE 37.112.103 DEFINITIONS (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.

(2) "Antiseptic" means a substance applied to the skin that kills or inhibits the growth of disease-causing microorganisms.

(3) "Artist" means a tattooist or body piercer.

(4) "Aseptic technique" means a procedure that prevents contamination of any object or person.

(5) "Body piercer" means a person who engages in the practice of piercing as defined in 50-48-102, MCA.

(6) "Body piercing establishment" means any room, space, shop, or salon, including a temporary or mobile facility, where body piercing is practiced.

(7) "Client" means the person whose skin will be tattooed or pierced.

(8) "Contaminated" means the probable presence of disease-causing microorganisms.

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

(10) "Disinfectant" means a substance or solution, registered with the United States Environmental Protection Agency (EPA), that kills or inactivates viruses and pathogenic microorganisms, but not necessarily their spores.

(11) "Ear lobe piercing" means the puncturing of the ear lobe, but not the ear cartilage, to create a permanent hole for cosmetic purposes.

(12) "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.

(13) "Infectious waste" means the definition found in 75-10-1003, MCA.

(14) "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.

(15) "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 procedure.

(16) "Jewelry" means any ornament designed for insertion into a pierced area of a client.

(17) "Mobile establishment" means a facility where tattooing or body piercing or both is conducted, utilizing a wheeled vehicle for movement from place to place.

(18) "Operator" means any owner of an establishment or any person who is responsible for the establishment as well as the other artists working at the establishment, for the purpose of meeting the requirements of this chapter.

(19) "Permanent cosmetics", also known as permanent makeup or micropigmentation, means tattooing any part of the face for cosmetic purposes.

(20) "Physician" means a person licensed to practice medicine in Montana by the Montana Board of Medical Examiners under the Department of Labor and Industry.

(21) "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.

(22) "Sharps" means any discarded instrument or article that may be contaminated with blood or other bodily fluid and may cause punctures or cuts, including but not limited to needles, scalpel blades, razors, and broken glass.

(23) "Single-use" means items that are intended to be used once then discarded.

(24) "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.

(25) "Tattoo establishment" means any room, space, shop, or salon, including a temporary or mobile facility, where tattooing is practiced.

(26) "Tattooist" means a person who engages in the practice of tattooing as defined in 50-48-102, MCA.

(27) "Temporary establishment" means a facility where either tattooing or body piercing or both are conducted for not more than 14 days at one location in a calendar year.

(28) "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.

(29) "Work room" means a designated room or area in which either tattooing or body piercing takes place.

RULE 37.112.108 GENERAL FACILITY REQUIREMENTS (1) Work rooms, restrooms, handwashing facilities, waiting areas, and all establishment areas to which clients have access must be kept clean and free of garbage, litter, unnecessary articles, dust, dirt, and sources of airborne dust or fumes.

(2) Utility rooms, storage rooms, and all other auxiliary rooms separated from other areas of the establishment by closed doors must be in good repair and cleaned as often as necessary to prevent insect or rodent harborage, airborne dust, airborne hazardous chemicals, or other contaminants.

(3) All rooms in the establishment must be provided with an artificial light source equivalent to 20 foot-candles of light three feet off the floor, except as required for work rooms in ARM 37.112.167(1)(b).

(4) An establishment may not be operated in any room or area used as living or sleeping quarters. An establishment must be separated from any living or sleeping quarters by solid self-closing doors.

RULE 37.112.109 WATER SUPPLY (1) An adequate and potable supply of water must be provided.

- (2) Before a license may be issued, an establishment using an individual, shared, or multiple user water supply must submit the following to the department or its designee:
- (a) satisfactory coliform bacteria and nitrate test results as specified in ARM 37, chapter 38, subchapter 2; and
 - (b) the results of an onsite sanitary survey of the water supply system to detect sanitary deficiencies.
- (3) A supplier of an individual, shared, or multiple user water supply shall conduct a coliform bacteria test of the system at least twice a year with one sample collected between April 1 through June 30 and the second sample collected between August 1 through October 31, and shall conduct a nitrate test of the system at least once every three years. Water tests must be analyzed at a certified laboratory. A supplier shall keep sampling result records for at least three years.
- (4) A public water supply system must be constructed and operated in accordance to current applicable laws as regulated by the Montana Department of Environmental Quality.
- (5) Nonpotable water sources must be marked "not for human consumption".
- (6) Plumbing must be installed and maintained in a manner to prevent cross connections between the potable water supply and any nonpotable or questionable water supply or any source of pollution through which the potable water supply might become contaminated. The potable water system must be installed to preclude the possibility of backflow. A hose may not be attached to a faucet unless a backflow prevention device is installed.
- (7) A water supply system is determined to have failed and requires treatment, replacement, repair, or disinfection, when the water supply becomes unsafe, when it exceeds the maximum contaminant levels specified in ARM Title 17, chapter 38, subchapter 2, or inadequate when it is found to be less than 20 psi measured at the extremity of the distribution line during the instantaneous peak usage.
- (8) Extension, alteration, repair, or replacement of a water supply system or development of a new water supply system must be in accordance with all applicable state and local laws.
- (9) Bottled and packaged potable water must be obtained from a licensed and approved source and shall be handled and stored in a way that protects it from contamination.

RULE 37.112.115 SEWAGE SYSTEM AND SOLID WASTE (1) An adequate and safe wastewater system must be provided for conveying, treating, and disposing of all sewage. Immediate measures must be taken to alleviate health and sanitation hazards caused by wastewater at the establishment when they occur.

(2) All sewage, including liquid waste, must be disposed of by a public sewage system approved by the Montana Department of Environmental Quality or by a sewage treatment and disposal system constructed and operated in accordance to applicable state and local laws. Nonwater-carried sewage disposal facilities are prohibited, except as permitted by ARM 37.112.121 for temporary or mobile establishments.

(3) A wastewater system has failed and requires replacement or repair if any of the following conditions occur:

- (a) the system fails to accept, treat, or dispose of wastewater as designed;
- (b) effluent from the wastewater system contaminates a potable water supply or state

waters; or

(c) the wastewater system is subjected to mechanical failure, including electrical outage, or collapse or breakage of a septic tank, lead line, or drainfield line.

(4) Extension, alteration, replacement, or repair of any wastewater system must be done in accordance with all applicable state and local laws.

(5) Mop water or soiled cleaning water may not be disposed of in any sink other than a mop or utility sink or a toilet.

(6) Solid waste must be collected, stored, and disposed of in a manner that does not create a sanitary nuisance and meets the requirements of ARM 37.112.137 for disposal of infectious waste. Solid waste must be removed from the premises at least weekly to a licensed solid waste disposal facility.

RULE 37.112.116 TOILETS AND HANDWASHING FACILITIES (1) Each establishment must have a toilet and handwashing facility conveniently available to clients and artists during all hours of operation.

(2) The toilet room must be located within 200 feet by a normal pedestrian route of the work room and not more than one floor-to-floor flight of stairs.

(3) The toilet room must be vented to the outside, well lighted, and equipped with a self-closing door, toilet tissue, and waste receptacle.

(4) Floors, walls, and ceilings of the toilet room must be in good repair and in clean condition.

(5) Equipment and supplies used for either tattooing or body piercing or both must not be stored or used within the toilet room.

(6) The handwashing facility must be located either within the toilet room or within ten feet of the toilet room door.

(7) 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) for temporary or mobile establishments.

(8) 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.

(9) Steam mixing valves are prohibited.

(10) Soap must be conveniently located to the hand sink.

(11) Single-use towels must be conveniently located for drying hands and a waste receptacle provided.

RULE 37.112.117 WORK ROOM REQUIREMENTS (1) All tattooing and body piercing 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 work room, except for patrol dogs accompanying security or police officers and service animals such as guide dogs.

(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. If heating ducts, vents, or air conditioners discharge into the work room, the intakes for such venting must be filtered, and the filters must be maintained to minimize airborne dust and insects.

(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) The work rooms must have a handwashing facility unless there is handwashing facility outside the work room within ten feet of the work room door.

(a) If the handwashing facility is outside the work room, the work room door must be a two-way self-closing door.

(b) If controls for wrist or foot activation are not available, single service towels must be used for turning controls off after washing hands.

(c) The handwashing sink must be sanitized at least once each day while the establishment is in operation.

(d) 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.

(e) 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.

(f) Steam mixing valves are prohibited.

(g) Soap must be conveniently located near the handwashing sink.

(h) Single-use 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 covered except while in use to prevent contamination of hands and gloves.

(b) Waste receptacles in the work room must be emptied daily.

(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 and must be wet-mopped daily.

(12) Tobacco use, eating, or drinking is prohibited in the work room, except eating and drinking is allowed when needed for first aid purposes.

RULE 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.

RULE 37.112.125 EQUIPMENT AND SUPPLIES (1) Equipment, tools, and jewelry must be clean, in sound condition, and free of rust. Sharp instruments and tools must not be dull. Defective needles may not be used.

(2) Single-use or disposal items must be used only once.

(3) Gloves that come into contact with a client must be single-use nonlatex examination gloves designed for medical or clinical use.

(4) A durable tray must be maintained in the work room for the placement of used articles which require cleaning and autoclaving.

(5) Single-use needles must be disposed of in a sharps disposal container that meets the requirements in ARM 37.112.137(2).

(6) Work tables, counter tops, and client contact surfaces must be:

(a) constructed of material that is easily cleanable, smooth, nonabsorbent, and corrosion-resistant; and

(b) cleaned and sanitized with a disinfectant between clients.

(7) The operator must maintain at all times enough sterile supplies, disinfectant, antiseptic, and gloves for three working days.

(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) Instruments, supplies, and other materials that come into contact with the client must be stored in closed clean containers or clean cabinets.

(10) Tables, trays, and equipment may not be shared among artists serving different clients at the same time.

RULE 37.112.129 BLOOD-BORNE PATHOGEN EXPOSURE CONTROL (1) An establishment operator employing at least one 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. Copies of 29 CFR 1910.1030 may be obtained by contacting the Montana Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

RULE 37.112.131 STERILIZATION OF EQUIPMENT AND JEWELRY (1) All

nondisposable instruments used for tattooing or body piercing 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.

(2) All jewelry must be sterilized or disinfected by at least one of the following methods:

(a) individually wrapped and autoclaved;

(b) come from the supplier individually wrapped and sterile; or

(c) be disinfected by complete immersion in 70% alcohol.

(3) Whenever an autoclave is used, the following requirements apply:

(a) Autoclave packaging and a testing indicator for verifying temperatures must be used each time.

(b) The autoclave must be allowed to run a complete cycle for 20 minutes at 15 pounds of pressure at a temperature of 250°F (121°C), or in accordance with the autoclave manufacturer's instructions.

(c) After autoclaving, the package must be dated and initialed by the 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) Monthly biological monitoring must be conducted on the autoclave using standard spore units that are analyzed by a certified laboratory.

(e) Following sterilization, equipment, and jewelry must remain in the autoclave packaging.

(4) Sterile packages must be opened in full view of the client.

(5) Jewelry that is sterilized by a chemical sterilant must be immediately inserted into the client to prevent possible contamination.

RULE 37.112.132 CLEANING AND ULTRASONIC USE (1) All nondisposable instruments used for tattooing and body piercing procedures must be cleaned thoroughly with an appropriate soap or detergent and rinsed completely with potable water.

(2) Each establishment must have at least a one-compartment sink with hot and cold running water for the cleaning of instruments. The sink must be of an adequate size to submerge the instruments being cleaned, except as provided in (3) of this rule.

(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 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) Ultrasonic unit use, cleaning, dusting, or vacuuming is prohibited during times when clients are being tattooed or pierced.

RULE 37.112.133 SKIN PREPARATION, ASEPTIC TECHNIQUE AND AFTERCARE

(1) Aftercare instructions appropriate for the tattooing or body piercing 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 procedure, artists shall use sterile instruments as specified in 37.112.125 and aseptic techniques.

(3) Before and after performing the tattooing or body piercing procedure, artists shall thoroughly wash their hands and wrists in warm running water with soap for at least 20 seconds, scrubbing around and under their fingernails, rinsing completely, and drying with a clean single-use towel.

(4) Artists shall wear a clean outer garment. A hair restraint must be worn if necessary to prevent the artist's hair from contact with the client. All necklaces, bracelets, or other personal items of the artist 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 artist shall use single-use razors. Straight razors and replaceable blade units may not be used. After shaving the client's skin, the artist shall:

(a) wash and scrub the artist's hands as described in (3) of this rule; and

(b) wash and rinse the client's area of skin that was shaved.

(6) If the artist wore gloves to wash or shave the client's skin, the artist shall discard those gloves after completing those tasks. The artist shall then put on a new pair of gloves before continuing the procedure.

(7) Before performing the tattooing or piercing 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 must be used only once.

(9) New gloves must be put on before each tattooing and piercing procedure.

(10) If the artist's gloved hands become contaminated during the tattooing or body piercing procedure, then the artist shall rewash hands and reglove 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 artist sustains a needle stick, the artist shall resume the tattooing or body piecing procedure with clean and sterile equipment after rewashing hands and regloving.

(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) Upon completion of the tattooing or piercing procedure, artists shall apply an antiseptic solution to the procedure area with a clean single-use cotton ball, gauze, or tissue.

RULE 37.112.137 HANDLING AND DISPOSAL OF INFECTIOUS MATERIAL

(1) Waste that may have been contaminated with blood or body fluids must be separated from other waste in different containers with biohazard warning labels.

(2) An adequate supply of sharps containers must be maintained on the premises. A sharps container must:

(a) be leakproof, rigid, and strong enough to protect the handler and others from accidental cuts or puncture wounds; and

(b) be closed or capped securely to prevent the loss of contents for disposal.

- (3) Waste that may have been contaminated with blood or body fluids, other than sharps, must be placed in moisture-proof single-use containers or bags of a strength sufficient to prevent ripping, tearing, or bursting under normal conditions of use. Also, the bags must be:
- (a) securely tied to prevent leakage or the expulsion of solid or liquid wastes during storage, handling, and transportation; and
 - (b) placed in a durable, leakproof container for storage and transportation.
- (4) An artist shall 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 artist shall wash hands and reglove as described in ARM 37.112.133 before working with a client.
- (5) Laundry that may have been contaminated with blood or body fluids must be stored separately in a leakproof and closed container or bag prior to cleaning.
- (6) All infectious waste must be treated and disposed of in accordance with Title 75, chapter 10, part 10, MCA.

RULE 37.112.141 RECORD KEEPING AND REVIEW (1) Client records, consent forms, autoclave sterilization test results, and any other records required by this chapter must be maintained on the establishment premises for a minimum of three years. The records must be:

- (a) available for review and verification by the department or its designee; and
 - (b) typed or printed in ink.
- (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.

RULE 37.112.142 CLIENT RECORD (1) The operator must maintain a client record for each client. At a minimum, the client record must include:

- (a) a copy of the signed consent form required by ARM 37.112.144;
- (b) the name of the artist who performed the tattooing or body piercing procedure;
- (c) the address and telephone number of the establishment;
- (d) special instructions or information regarding the client's medical or skin conditions which are relevant to the tattooing or body piercing procedure; and
- (e) a written physician referral if one is required by ARM 37.112.158.

RULE 37.112.144 CONSENT FORM (1) The client must sign a consent form before each tattooing or body piercing 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) The consent form must contain:
- (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 artist may consider appropriate;
 - (b) a description of potential complications and side-effects, including abscesses,

allergies, excessive bleeding (from body piercing), heavy metal poisoning, infection, keloid formation, muscle paralysis, nerve paralysis, scarring, swelling, and tooth fracture (from oral piercing).

- (c) symptoms of infection such as fever, swelling, redness, or drainage;
- (d) instructions to consult a physician if symptoms of infection or other complications occur;
- (e) the permanent nature of either tattoos or specific piercings or both; and
- (f) a statement by the client that the client:
 - (i) has been provided with the preservice information, both in writing and verbally by the artist; and
 - (ii) consents to the tattooing or body piercing procedure.

RULE 37.112.147 TRAINING (1) Operators and artists shall complete formal training provided by the department or its designee that includes at least general sanitation, first aid, and universal precautions for preventing the transmission of blood-borne pathogens.

(2) Operators shall complete formal training within one year prior to obtaining a license from the department, and at least once in each calendar year of license renewal thereafter. Artists shall complete formal training within 60 days of hire, contract, or apprenticeship with an operator, and at least once every calendar year thereafter.

(3) Equivalent formal training that is not provided by the department or its designee may be permitted if the training contains the same subject matter requirements as specified in (1), and the department or its designee has approved the training.

(4) Each formal training course must provide written documentation to trainees indicating successful completion the course.

RULE 37.112.150 LICENSE REQUIREMENT AND DISPLAY (1) No person shall operate an establishment without a license issued by the department. Only a person who complies with the requirements of this chapter shall be entitled to receive or retain such a license. Licenses are not transferable.

(2) A valid license must be posted in every establishment in a conspicuous location.

RULE 37.112.151 LICENSE APPLICATION (1) Any person desiring to operate an establishment shall submit an application for a license on forms provided by the department. The application must include the name and address of the applicant, and the location and type of the proposed establishment.

(2) The applicant of license and all artists working in the proposed establishment shall be at least 18 years of age at the time of application.

(3) Prior to approval of an application for a license, the department or its designee will inspect the proposed establishment to determine compliance with the requirements of this chapter.

(4) The department will issue a license to the applicant if the applicant demonstrates that the proposed establishment complies with all applicable requirements of this chapter by plan review, inspection, and upon receipt of the license fee.

(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) building code permits and inspections;
- (b) fire and life safety inspections; and
- (c) other business licenses.

RULE 37.112.152 LICENSE FEE AND EXPIRATION (1) Except as provided in (2), the license fee is \$135.

- (2) The license fee for establishments that only pierce ear lobes is \$75.
- (3) The license will expire annually on December 31 following the date of its issuance.

RULE 37.112.153 LICENSE DENIAL AND CANCELLATION (1) A notice of license denial or cancellation, as provided for in 50-48-205, MCA, is properly served when it is hand-delivered to the operator of the license or the person in charge, or when it is sent by registered or certified mail to the last known address of the operator.

(2) The hearing process provided in 50-48-205, MCA, concerning license denial or cancellation, must be conducted by the department pursuant to Title 2, chapter 4, part 6, MCA, of the Montana Administrative Procedure Act regarding contested cases, and ARM 37.5.117.

RULE 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) 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 37.121.147.

(3) If the department or its designee disapproves of the plans, the department or its designee will make the deficiencies known to the applicant.

(4) If the facility was previously licensed or certified by the department as a tattooing or body piercing establishment and no structural modification is involved, the department may waive the requirement for the submission of plans.

(5) Changes in the client consent form, client record form, and all applicable aftercare instructions must be submitted to the department or its designee before implementation.

RULE 37.112.157 INSPECTION (1) The department or its designee, after proper

identification, must be permitted to enter any establishment at any reasonable time for the purpose of making inspections to determine compliance with this chapter and must be permitted to examine the records of the establishment pertaining to compliance with this chapter.

(2) The department or its designee shall conduct inspection of establishments at least once per year. Additional inspections of the establishment may be performed as often as necessary for the enforcement of this chapter. The department will charge a follow-up fee for a third or subsequent inspection if a violation of this chapter is not corrected by the end of the second visit to the establishment. The follow-up fee is \$150.

(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.

(a) Correction of the violations that the department or its designee finds must be accomplished within the period specified on the inspection form.

(b) Failure to comply with any time limits for corrections of critical item violations may result in cessation of establishment operations.

(c) The completed inspection report form is a public document that must be made available for public review or distribution upon payment of reasonable copying costs.

RULE 37.112.158 RESTRICTIONS AND PROHIBITIONS (1) A tattooing or body piercing procedure may not occur if:

(a) either the artist or the client is under the apparent influence of alcohol or other mind-altering drugs;

(b) the client has not signed the consent form required by ARM 37.112.144; or

(c) the client is under the age of 18, without the explicit in-person consent of the client's parent or legal guardian as provided in 45-5-623, MCA.

(2) If the client is under the age of 18, the parent or legal guardian must accompany the client throughout the procedure.

(3) A written physician referral is required before tattooing or body piercing if the client:

(a) is taking any drug or dietary supplements that may induce bleeding tendencies or reduce clotting;

(b) has a medical condition that is known to cause bleeding tendencies or reduce clotting;

(c) shows signs of recent intravenous drug use;

(d) has a sunburn, a skin disease such as psoriasis or eczema, a skin infection, or lesions such as a mole in the proposed procedure site; or

(e) discloses or evidences allergies or contact sensitivity to pigments, soaps, or other substances that may be used in the procedure.

(4) The artist may delay or require a medical referral before conducting any tattooing or piercing for any person whose physical health, understanding, or judgment may be in question.

RULE 37.112.159 VARIANCE (1) A licensee may request a variance to waive or

modify compliance with the health requirements of this chapter by petitioning the department. An application for a variance must contain:

(a) a statement of the proposed variance from the chapter's requirements, citing the relevant rule numbers; and

(b) a rationale explaining how the potential public health hazards addressed by the relevant rules will be alternatively addressed by the proposal.

(2) The department may grant a variance by modifying or waiving the requirements of this chapter if, in the opinion of the department, a health hazard will not result from the variance.

(3) A licensee must continuously demonstrate compliance with the variance or modification granted by the department. The failure to comply to the department-approved variance or modification may be grounds for license revocation.

(4) The department reserves the right to deny or revoke a variance if, in its judgment, a health risk may occur.

RULE 37.112.162 TATTOOING: PATTERN TRANSFER (1) If the method of pattern transfer involves a reusable plastic or acetate stencil, the stencil must be cleaned and sanitized immediately prior to the application.

(2) An adherent or emollient applied to facilitate a pattern transfer, or to cover a pattern after transfer, must be from a single-use container or must be extracted from a supply container in a manner to prevent contamination of the adherent or emollient supply.

RULE 37.112.163 TATTOOING: COLORS, DYES, AND PIGMENTS (1) Each tattooist shall use colors, dyes, and pigments from reputable suppliers, designed for tattooing, stored in appropriate clean and sterile containers, and labeled with the manufacturer name and lot number.

(2) Pigments mixed or prepared in the tattoo establishment must be prepared and stored in accordance with the manufacturer's instructions.

(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, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951 or the local health officer. 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) Pigments or dyes may not be used if they are disapproved of or under recall by the United States Food and Drug Administration or the department under the Montana Food, Drug and Cosmetic Act, Title 50, Chapter 31, MCA.

(5) Individual pigment portions and ink cups must be used for one client, then disposed in accordance with ARM 37.112.137 pertaining to infectious waste.

(6) If additional pigment must be added to an ink cup during the tattooing, the tattooist shall wash hands and reglove, or use a single-use liner to handle the ink storage container.

RULE 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) 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 1;
- (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;
- (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.

RULE 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 approved by the department or its designee may be exempted from ARM 37.112.116(2), 37.112.117(2), 37.112.117(5), and 37.112.117(8) as long as:

- (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
- (c) the artist and client must have convenient access to handwashing facilities. If the handwashing facility is not within the work room or within ten feet of the work room door, then an 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 hereby adopts and incorporates 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 Montana Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.