

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)(w) (16 **Del.C.** §122(3)(w))
16 **DE Admin. Code** 4451

FINAL

ORDER

4451 Body Art Establishments

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Body Art Establishments. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code**, §§122(3)(w).

On November 1, 2014 (Volume 18, Issue 5), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by December 10, 2014, or be presented at a public hearing on November 25, 2014, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

No oral comments were made at the public hearing and no written comments were received during the public comment period. Therefore, no evaluation or summarization of comments is presented in the accompanying "Summary of Evidence".

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) State of Delaware Body Art Establishments were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*.

The public comment period was open from November 1, 2014 through December 10, 2014. No comments were received on the proposed regulations during the public comment period and no changes have been made to the proposed regulations.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

There were no public comments received. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Body Art Establishments is adopted and shall become effective February 11, 2015, after publication of the final regulation in the *Delaware Register of Regulations*.

Rita M. Landgraf, Secretary

4451 Body Art Establishments

1.0 General Provisions

- 1.1 Preamble. The Secretary of Delaware Health and Social Services adopts these Regulations pursuant to the authority vested in the Secretary by 16 **Del.C.** §122. These Regulations establish standards for the sanitary operation of body art establishments. For the purpose of these Regulations, the term "body art establishment" includes "tattoo parlor" and "body piercing establishment," as defined in 16 **Del.C.** §122(3)(w). These Regulations provide a system of permitting and inspection of body art establishments and procedures for enforcement.

~~These Regulations are adopted on November 1, 2011 and have an effective date of November 11, 2011.~~

- 1.2 Purpose. These Regulations shall be liberally construed and applied to promote their underlying purpose of protecting the public health. They set forth minimum standards in the practice of body art and those establishments that choose to require more stringent standards are encouraged to do so.

- 1.3 Severability. In the event any particular clause or section of these Regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.
- 1.4 Exemptions
- 1.4.1 Licensed health care practitioners allowed by law to provide medical treatment who perform body art procedures either independent of or in connection with patient treatment are exempt from these regulations.
- 1.4.2 Individuals who pierce only the outer perimeter and lobe of the ear using a pre-sterilized single use stud and clasp ear piercing system are exempt from these Regulations. Individuals who use ear piercing systems must conform to the manufacturer's directions on use and applicable U.S. Food and Drug Administration requirements. The Division retains authority to investigate consumer complaints relating to alleged misuse or improper disinfection of ear piercing systems.
- 1.5 Variance
- 1.5.1 A licensee may seek a variance from these Regulations by making a request for variance to the Division. The Division may grant a variance by modifying or waiving the requirements of these Regulations if in the opinion of the Division a health hazard or nuisance will not result from the variance.
- 1.5.2 A variance shall not be transferable from person to person, nor from location to location.
- 1.5.3 If a variance is granted, the Division shall retain the information specified below in its records for the Body Art establishment.
- 1.5.3.1 A statement of the proposed variance of the requirement of these Regulations, citing the relevant section of these Regulations;
- 1.5.3.2 An analysis of the rationale for how the potential public health hazards or nuisances will be alternatively addressed by the proposal; and
- 1.5.3.3 Any other information requested by the Division that may be deemed necessary to render judgment.
- 1.5.4 A variance is rendered void upon occurrence of one or more of the following: the physical facility is demolished; a remodeling project in the facility includes the area(s) addressed in the variance; or the permit holder granted the variance ceases to operate the body art establishment for a period exceeding thirty (30) consecutive days.

2.0 Definitions

For the purposes of these Regulations the following definitions apply:

"Aftercare" means written instructions given to the client, specific to the body art procedure(s) rendered, on caring for the body art and surrounding area. These Instructions will include information on when to seek medical treatment, if necessary.

"Antiseptic" means an agent that destroys disease causing microorganisms on human skin or mucosa.

"Body Art" includes the practice of "body piercing" as defined, "branding" as defined and "tattooing" as defined. This definition does not include practices that are considered medical procedures by a state medical board, such as implants under the skin and subdermal piercing/implants, that are not performed in a body art establishment. Nor does this definition include, for the purposes of these Regulations, piercing of the outer perimeter or lobe of the ear using pre-sterilized single use stud and clasp ear piercing systems.

"Body Art Establishment" includes "tattoo parlor" and "body piercing establishment" and means any place or premise, whether public or private, temporary or permanent in nature or location, where the practices of body art, whether or not for profit, are performed.

"Body Piercing" means the perforation of human tissue excluding the ear for a non-medical purpose. This definition does not include subdermal piercings / implants.

"Branding" means a permanent mark made on human tissue by burning with chemicals such as liquid nitrogen, with a hot iron or with another instrument.

"Contaminated Waste" means any of the following: any liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; sharps and any wastes containing blood and other potentially infectious materials, as defined in "Occupational Exposure to Bloodborne Pathogens", 29 Code of Federal Regulations Part 1910.1030 (latest edition).

"Cosmetic Tattooing" see Tattooing.

“Disinfection” means the destruction of disease-causing microorganisms on inanimate objects or surfaces, thereby rendering these objects safe for use or handling.

“Division” means the Delaware Division of Public Health as the agency, and its authorized representatives, having jurisdiction to promulgate, monitor, administer and enforce these Regulations.

“Ear Piercing” means the puncturing of the outer perimeter or lobe of the ear using a pre-sterilized single use stud and clasp ear piercing system following manufacturer’s instructions. Under no circumstances shall ear piercing studs and clasps be used anywhere on the body other than the outer perimeter and lobe of the ear.

“Equipment” means all machinery, including fixtures, containers, vessels, tools, devices, implements, furniture, display and storage areas, sinks and all other apparatuses and appurtenances used in connection with the operation of a body art establishment.

“Handsink” means a lavatory equipped with tempered hot and cold running water under pressure, used solely for washing hands, arms or other portions of the body.

“Hot Water” means water at a temperature greater than or equal to 110°F (43°C).

“Imminent Health Hazard” means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity and duration of the anticipated injury.

“Instruments Used For Body Art” means hand pieces, needles, needle bars and other instruments that may come in contact with a client’s body or possible exposure to bodily fluids during body art procedures.

“Invasive” means entry into the body either by incision or insertion of an instrument into or through the skin or mucosa, or by any other means intended to puncture, break or compromise the skin or mucosa.

“Jewelry” means any personal ornament inserted into a newly pierced area, which must be made of surgical implant grade stainless steel, solid 14k, 18k or 24k white or yellow gold, niobium, titanium, platinum, or a dense, low-porosity plastic and which is free of nicks, scratches or irregular surfaces and which has been properly sterilized prior to use.

“Liquid Chemical Germicide” means a disinfectant or sanitizer registered with the Environmental Protection Agency or an approximate 1:100 dilution of household chlorine bleach made fresh daily and dispensed from a spray bottle (500 ppm, ¼ cup per gal. or 2 tablespoons per qt. of tap water).

“Operator/technician” means any person who controls, operates, manages, conducts or practices body art activities at a body art establishment and who is responsible for compliance with these regulations, whether actually performing body art activities or not. The term includes technicians who work under the operator and perform body art activities.

“Permit” means written approval by the Division to operate a body art establishment. Approval is given in accordance with these Regulations and is separate from any other licensing requirement that may exist within communities or political subdivisions comprising the jurisdiction.

“Person” means an individual, any form of business or social organization or any other non-governmental legal entity including but not limited to a corporation, partnership, limited liability company, association, trust or unincorporated organization.

“Physician” means a person licensed by the State of Delaware to practice medicine in all its branches and may include other areas such as dentistry, osteopathy or acupuncture, depending on the rules and regulations of the State of Delaware.

“Procedure Surface” means any surface of an inanimate object that contacts one or more of the following: a client’s unclothed body during a body art procedure; skin preparation of the area adjacent to and including the body art procedure; or any associated work area which may require sanitizing.

“Sanitize/Sanitization Procedure” means a process of reducing the numbers of microorganisms on cleaned surfaces and equipment to a safe level as judged by public health standards and which has been approved by the Division.

“Sharps” means any object (sterile or contaminated) that may purposefully or accidentally cut or penetrate the skin or mucosa including, but not limited to, pre-sterilized, single use needles, scalpel blades and razor blades.

“Sharps Container” means a puncture-resistant, leak-proof container that can be closed for handling, storage, transportation and disposal and is labeled with the International Biohazard Symbol.

“Single Use” means products or items that are intended for one-time, one-person use and are disposed of after use on each client including, but not limited to, cotton swabs or balls, tissues or paper products, paper or plastic cups, gauze and sanitary coverings, razors, piercing needles, scalpel blades, stencils, ink cups and protective gloves.

“Sterilization” means a very powerful process resulting in the destruction of all forms of microbial life, including highly resistant bacterial spores.

“Tattooing” means one or more of the following:

- An indelible mark made upon the body of another person by the insertion of a pigment under the skin;
- An indelible design made upon the body of another person by production of scars other than by branding;
- All forms of cosmetic tattooing.

“Temporary Body Art Establishment” means any place or premise operating at a fixed location where an operator performs body art procedures for no more than 14 days consecutively in conjunction with a single event or celebration.

“Universal Precautions” means a set of guidelines and controls, published by the Centers for Disease Control and Prevention (CDC) as 'guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers' in Morbidity and Mortality Weekly Report (MMWR), June 23, 1989, Vol. 38, No. S-6, and as 'recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures', in MMWR, July 12, 1991, Vol. 40, No. RR-8. This method of infection control requires the employer and the employee to assume that all human blood and specified human body fluids are infectious for HIV, HBV and other blood pathogens. Precautions include hand washing, gloving, using personal protective equipment, injury prevention, and proper handling and disposal of needles, other sharp instruments, and blood and body fluid contaminated products.

3.0 Preoperational Requirements

3.1 Permits

- 3.1.1 No person shall operate a body art establishment who does not have a valid permit issued by the Division. Only a person who complies with the requirements of these Regulations shall be entitled to receive or retain such a permit.
- 3.1.2 An establishment's valid permit shall be posted in a location easily observed by the customer.
- 3.1.3 Permits shall not be transferable from person to person or from location to location.
- 3.1.4 When a body art establishment changes ownership, management firm, or lessee, both the facility and its operation shall be brought into full compliance with these Regulations prior to the issuance of a permit. A variance may be issued, as provided by these Regulations.
- 3.1.5 Establishments in compliance with these Regulations shall be issued a permit in accordance with Section 3.2 of these Regulations. Establishments that continue to operate without proper permits from the Division or operate in violation of these Regulations will be subject to legal remedial actions and sanctions as provided by law.

3.2 Classification of Body Art Establishment Permits

- 3.2.1 Permanent permit – a permit issued for businesses that operate at a fixed location. A permanent permit is valid for one year from the date of issuance.
- 3.2.2 Mobile permit – a permit issued to an enclosed vehicle which meets all the requirements of these Regulations and which does not operate at a fixed location. A mobile permit is valid for one year from the date of issuance.
- 3.2.3 Temporary permit – a permit issued for educational, trade show or product demonstration purposes only. A temporary permit is valid for fourteen (14) calendar days from the date of issuance.
- 3.2.4 Restricted permit – a permit issued to an establishment that is not approved to provide full services because of certain limitations. A restricted permit shall not be valid for longer than one year from the date of issuance.

3.3 Issuance of Permits

- 3.3.1 Any person desiring to operate a body art establishment shall make written application for a permit. Such application shall be made on forms provided by the Division and shall include the name and address of each applicant, the location and type of the proposed establishment and the signature of each applicant. Payment of a \$100 fee shall accompany the application and be remitted with the initial or annual renewal application.
- 3.3.2 Upon issuance of an application and the fee, an applicant shall permit the Division to enter the proposed body art establishment to conduct an inspection.
- 3.3.3 The Division shall issue a permit to the applicant if its inspection reveals that the proposed body art establishment complies with these Regulations.

- 3.3.4 A permit is no longer valid upon occurrence of one or more of the following events: the establishment is closed for a period of sixty (60) days or more; a new owner, firm, or lessee takes possession of the establishment; or the permit is revoked by the Division for violation of these Regulations.

3.4 Submission of Plans

- 3.4.1 Whenever a body art establishment is constructed, undergoes physical alteration, or an existing structure is converted for this purpose, properly prepared plans and specifications shall be submitted to the Division. After review, a Certificate of Approval with conditions will be issued, and the establishment shall comply with the requirements.
- 3.4.2 Body art establishments applying for permit after adoption of these Regulations shall submit a scale drawing and floor plan of the proposed establishment for a plan review by the Division as part of the Permit Application process. The Division may charge a reasonable fee for this review.

4.0 Inspections

4.1 Inspections and Right of Access

- 4.1.1 The Division shall have the right of access to inspect a body art establishment to determine compliance with these Regulations upon occurrence of any of the following conditions:
 - 4.1.1.1 Prior to issuance of a permit;
 - 4.1.1.2 After a body art establishment is constructed, undergoes physical alteration, or an existing structure is converted into a body art establishment; or
 - 4.1.1.3 Upon receipt of a complaint or reasonable belief that a body art establishment is in violation of these Regulations.
 - 4.1.1.4 The Division shall inspect a body art establishment at least once every twelve (12) months.
- 4.1.2 A representative of the Division conducting an inspection shall provide notice of the intent to conduct an inspection. Upon arrival at the establishment the representative of the Division conducting the inspection shall present proper identification to the person in charge of the body art establishment. The person in charge of the body art establishment shall allow the representative to determine if the establishment is in compliance with these Regulations by allowing access to the establishment, allowing inspection, and providing information and records specified in these Regulations and to which the Division is entitled.

4.2 Division Personnel Competency Requirement

Division personnel performing environmental health/sanitary evaluations or complaint investigations of body art establishments shall meet the same requirements as specified for a permit holder in Section 5.2 of these Regulations prior to assuming responsibilities for this program.

5.0 Operational Requirements

5.1 Requirements for the Premises

- 5.1.1 All walls, floors, and all procedure surfaces in rooms or areas where body art procedures are performed shall be smooth, washable, and in good repair. Walls, floors and ceilings shall be maintained in a clean condition. All procedure surfaces, including client chairs/benches shall be of such construction as to be easily cleaned and sanitized after each client. All body art establishments shall be completely separated by solid partitions or by walls extending from floor to ceiling, from any room used for human habitation, a food establishment or room where food is prepared, a hair salon, or other such activity which may cause contamination of work surfaces.
- 5.1.2 Effective measures shall be taken by the body art operator/technician to protect the entrance into the establishment and the breeding or presence on the premises of insects, vermin and rodents. Insects, vermin and rodents shall not be present in any part of the establishment, its appurtenances or adjoining premises.
- 5.1.3 There shall be a minimum of forty-five (45) square feet of procedure area floor space for each operator/technician in the establishment. Each establishment shall have an area which may be screened from public view for clients requesting privacy. Multiple body art stations shall be separated by dividers, curtains or partitions, at a minimum.
- 5.1.4 The establishment shall be well-ventilated and provided with an artificial light source equivalent to at least twenty (20) foot candles three (3) feet off the floor, except that at least one hundred (100) foot candles shall be provided at the level where the body art procedure is being performed, and where instruments and sharps are assembled.
- 5.1.5 No animals of any kind shall be allowed in a body art establishment except service animals used by persons with disabilities. Fish aquariums shall be allowed in non-procedural areas.

- 5.1.6 A separate, readily accessible handsink with hot and cold running water, under pressure, preferably equipped with wrist or foot operated controls, supplied with liquid soap, and disposable paper towels shall be readily accessible within the body art establishment. One handsink shall serve no more than three operators/technicians. In addition, there shall be a minimum of one lavatory, excluding any service sinks, and one toilet in a body art establishment.
- 5.1.7 At least one waste receptacle shall be provided in each operator/technician area and each toilet room. Receptacles in the operator/technician area shall be emptied daily and solid waste shall be removed from the premises at least weekly. All refuse containers shall be cleanable and kept clean.
- 5.1.8 All instruments and supplies shall be stored in clean, dry and covered containers.
- 5.1.9 Reusable cloth items shall be mechanically washed with detergent and dried after each use. The cloth items shall be stored in a dry, clean environment until used.
- 5.2 Requirements for the Permit Holder
 - 5.2.1 The permit holder of the body art establishment shall have the ability to demonstrate knowledge of the following subjects:
 - 5.2.1.1 Skin diseases, disorders, and conditions (including diabetes);
 - 5.2.1.2 Universal Precautions, as published by the Centers for Disease Control and Prevention;
 - 5.2.1.3 Infectious disease control, including waste disposal, hand washing techniques, sterilization, equipment operation and methods, and sanitization, disinfection, and sterilization methods and techniques; and
 - 5.2.1.4 Facility safety and sanitation.
 - 5.2.2 The permit holder shall only hire operators/technicians who have complied with the requirements of these Regulations and who have the ability to demonstrate skills and knowledge in body art procedures.
- 5.3 Requirements for Professional Standards
 - 5.3.1 The following information shall be kept on file on the premises of a body art establishment and available for inspection by the Division.
 - 5.3.1.1 Information on employees:
 - 5.3.1.1.1 Full name;
 - 5.3.1.1.2 Date of birth;
 - 5.3.1.1.3 Gender;
 - 5.3.1.1.4 Home address;
 - 5.3.1.1.5 Home/work phone number;
 - 5.3.1.1.6 Identification photograph;
 - 5.3.1.1.7 If an operator/technician, written proof that the operator/technician has either completed or was offered and declined, the hepatitis B vaccination series; and
 - 5.3.1.1.8 Description of duties.
 - 5.3.1.2 Information on establishment:
 - 5.3.1.2.1 Name;
 - 5.3.1.2.2 Hours of operation;
 - 5.3.1.2.3 Owner's name and address; and
 - 5.3.1.2.4 Complete description of all body art procedures performed.
 - 5.3.1.3 Inventory of all instruments and body jewelry, all sharps, and all inks used for any and all body art procedures, including names of manufacturers and serial or lot numbers, if applicable. Invoices or orders shall satisfy this requirement.
 - 5.3.1.4 A copy of these regulations.
 - 5.3.2 It shall be unlawful for any person to perform body art procedures unless such procedures are performed in a body art establishment with a current permit.
 - 5.3.3 The body art operator/technician must be a minimum of eighteen (18) years of age.
 - 5.3.4 Smoking, eating, or drinking should be restricted in the area where body art is performed.
 - 5.3.5 Under the influence.
 - 5.3.5.1 No operator/technician shall tattoo, brand, or perform body piercing on a person if the person is under the influence of alcoholic beverages, including beer, wine or spirits, or a controlled substance.

- 5.3.5.2 No operator/technician shall tattoo, brand, or perform body piercing on a person if the operator/technician is under the influence of alcoholic beverages, including beer, wine or spirits, or a controlled substance.
- 5.3.6 The permit holder and all employees shall comply with Universal Precautions, as defined in these Regulations, and shall assume that all human blood and specified human body fluids are infectious for HIV, HBV, and other blood pathogens.
- 5.3.7 The operator/technician shall maintain a high degree of personal cleanliness, conform to hygienic practices and wear clean clothes when performing body art procedures. Before performing body art procedures, the operator/technician must thoroughly wash their hands in hot running water with liquid soap, then rinse hands and dry with disposable paper towels. This shall be done as often as necessary to remove contaminants.
- 5.3.8 In performing body art procedures, the operator/technician shall wear disposable medical gloves. Gloves must be changed if they become contaminated by contact with any non-clean surfaces or objects or contact with a third person. The gloves shall be discarded, at a minimum, after the completion of each procedure on an individual client and hands washed prior to donning the next set of gloves. Under no circumstances shall a single pair of gloves be used on more than one person. The use of disposable medical gloves does not preclude or substitute for hand washing procedures as part of a good personnel hygiene program.
- 5.3.9 If, while performing a body art procedure, the operator's/technician's glove is pierced, torn or otherwise contaminated, the procedures in Sections 5.3.7 and 5.3.8 of these Regulations shall be repeated. The contaminated gloves shall be immediately discarded and the hands washed thoroughly, per Section 5.3.6, before a fresh pair of gloves is applied. Any item or instrument used for body art which is contaminated during the procedure shall be discarded and replaced immediately with a new disposable item or a new sterilized instrument or item before the procedure resumes.
- 5.3.10 Contaminated waste, as defined in these Regulations, which releases liquid blood or body fluids when compressed or releases dried blood or body fluids when handled must be placed in an approved "red" bag which is marked with the International Biohazard Symbol. It must then be disposed of by a waste hauler approved by the Delaware Department of Natural Resources and Environmental Control. Sharps ready for disposal shall be disposed of in approved sharps containers. Contaminated waste which does not release liquid blood or body fluids when compressed or does not release dried blood or body fluids when handled may be placed in a receptacle and disposed of through normal, approved disposal methods. Storage of contaminated waste on-site shall not exceed the period specified by the Division or more than a maximum of 30 days, as specified in 29 Code of Federal Regulations Part 1910.1030, whichever is less.
- 5.3.11 Any skin or mucosal surface to receive a body art procedure shall be free of rash or any visible infection.
- 5.3.12 The skin of the operator/technician shall be free of rash or infection. No person or operator/technician affected with boils, infected wounds, open sores, abrasions, keloids, weeping dermatological lesions or acute respiratory infection shall work in any area of a body art establishment in any capacity in which there is a likelihood that they could contaminate body art equipment, supplies or working surfaces with body substances or pathogenic organisms.
- 5.3.13 Proof shall be provided upon request of the Division that all operators/technicians have either completed or were offered and declined, in writing, the hepatitis B vaccination series. This offering should be included as a pre-employment requirement.
- 5.4 Requirements for Preparation and Care of the Body Art Area
- 5.4.1 Before performing a body art procedure, the immediate and surrounding area of the skin where the body art procedure is to be placed shall be washed with soap and water or an approved surgical skin preparation, depending on the type of body art to be performed. If shaving is necessary, single-use disposable razors or safety razors with single service blades shall be used and discarded after each use and the reusable holder shall be autoclaved after use. Following shaving, the skin and surrounding area will be washed with soap and water. The washing pad shall be discarded after a single-use.
- 5.4.2 In the event of blood flow, all products used to check the flow of blood or to absorb blood shall be single-use and disposed of immediately after use in appropriate containers, unless the disposal products meet the definition of Contaminated Waste.
- 5.5 Requirements for Sanitation and Sterilization Procedures
- 5.5.1 All non-single-use, non-disposable instruments used for body art shall be cleaned thoroughly after each use by scrubbing with an appropriate soap or disinfectant solution and hot water or follow the manufacturer's instructions to remove blood and tissue residue, and placed in an ultrasonic unit which will also be operated in accordance with manufacturer's instructions.

- 5.5.2 After cleaning, all non-disposable instruments used for body art shall be packed individually in peel-packs and subsequently sterilized. All peel-packs shall contain either a sterilizer indicator or internal temperature indicator. Peel-packs must be dated with an expiration date not to exceed six (6) months.
- 5.5.3 All cleaned, non-disposable instruments used for body art shall be sterilized in a steam autoclave. The sterilizer shall be used, cleaned, and maintained according to manufacturer's instruction. A copy of the manufacturer's recommended procedures for the operation of their sterilization unit must be available for inspection by the Division. Sterile equipment may not be used if the package has been breached or after the expiration date without first repackaging and resterilizing. Sterilizers shall be located away from work stations or areas frequented by the public. If the body art establishment uses all single-use, disposable instruments and products, and utilizes sterile supplies, an autoclave shall not be required.
- 5.5.4 Each holder of a permit to operate a body art establishment shall demonstrate that the sterilizer used is capable of attaining sterilization by spore destruction tests every 30 days. These tests shall be verified through an independent laboratory. The permit shall not be issued or renewed until documentation of the sterilizer's ability to destroy spores is received by the Division. These test records shall be retained by the operator for a period of three (3) years and made available to the Division upon request. If the Division determines that the establishment was open when a current sterile spore destruction test was not available, then an administrative penalty of \$100 each day that the establishment was open may be assessed.
- 5.5.5 All reusable needles used in tattooing and body piercing shall be cleaned and sterilized prior to use and stored in peel-packs. After sterilization, the instruments used for tattooing and body piercing shall be stored in a dry, clean cabinet or other tightly covered container reserved for the storage of such instruments.
- 5.5.6 All instruments used for tattooing and body piercing shall remain stored in sterile packages until just prior to performing a body art procedure. When assembling instruments used for performing body art procedures, the operator/technician shall wear disposable medical gloves and use medically recognized techniques to ensure that the instruments and gloves are not contaminated.
- 5.5.7 All inks, dyes, pigments, needles and equipment shall be specifically manufactured for performing body art procedures and shall be used according to manufacturer's instructions. The mixing of approved inks, dyes or pigments or their dilution with potable water is acceptable. Immediately before applying a tattoo, the quantity of the dye to be used shall be transferred from the dye bottle and placed into single-use paper cups or plastic cups. Upon completion of the tattoo, these single-use paper cups or plastic caps and their contents shall be discarded.
- 5.6 Requirements for Single-use Items
 - 5.6.1 Single-use items shall not be used on more than one client for any reason. After use, all single-use needles, razors, razor blades, and other sharps shall be immediately disposed of in approved sharps containers.
 - 5.6.2 All products applied to the skin, including body art stencils shall be single-use and disposable. Acetate stencils shall be allowed for re-use if sanitization procedures are performed between uses if approved by the Division. Petroleum jellies, soaps and other products used in the application of stencils shall be dispensed and applied on the area to be tattooed with sterile gauze or in a manner to prevent contamination of the original container and its contents. The gauze shall be used only once and then discarded.

6.0 Notification and Records Requirements

- 6.1 Public Notification Requirements
 - 6.1.1 Verbal and written public educational information, approved by the Division, shall be required to be given to all clients wanting to receive body art procedure(s). Verbal and written instructions, approved by the Division, for the aftercare of the body art procedure site shall be provided to each client by the operator/technician upon completion of the procedure. The written instructions shall advise the client to consult the operator/technician at the first sign of infection or swelling and contain the name, address and phone number of the establishment. These documents shall be signed and dated by the applicant. The establishment shall retain the original signed and dated documents along with all other required records.
 - 6.1.2 The establishment shall prominently display a Disclosure Statement, provided by the Division, which advises the public of the risks and possible consequences of body art services.
 - 6.1.3 The establishment's permit holder shall post in public view the name, address and phone number of the Division, and the procedure for filing a complaint.
- 6.2 Client Records

- 6.2.1 In order for the operator/technician to properly evaluate the client's medical condition for receiving a body art procedure and not violate the client's rights or confidential medical information, the operator/technician shall obtain the following information from the client:
- "In order for proper healing of your body art procedure, we ask that you disclose if you have or have had any of the following conditions:
- (a) Diabetes;
 - (b) History of hemophilia (bleeding);
 - (c) History of skin diseases, skin lesions or skin sensitivities to soaps, disinfectants;
 - (d) History of allergies or adverse reactions to pigments, dyes or other skin sensitivities;
 - (e) History of epilepsy, seizures, fainting or narcolepsy;
 - (f) Taking medications such as anticoagulants which thin the blood and/or interferes with blood clotting."
- 6.2.2 The operator/technician shall require the client to sign a Release Form confirming that the above information was obtained or attempted to be obtained. The client should be asked to disclose any other information that would aid the operator/technician in the client's body art healing process evaluation.
- 6.2.3 Each body art establishment shall keep records of all body art procedures administered including date, identification and location of the body art procedure(s) performed, and operator's/technician's name. All client records shall be confidential and be retained for a minimum of three (3) years from the date of service and made available to the Division upon request.
- 6.2.4 Nothing in this section shall be construed to require the operator/technician of a body art establishment to perform a body art procedure upon a client.

6.3 Records Retention

- 6.3.1 The body art establishment shall keep a record of all persons who have had body art procedures performed. The record shall include the name, date of birth, and address of the client, the date of the procedure, name of operator/technician who performed the procedure(s), type and location of procedure performed, signature of client and if the client is a minor, proof of parental or guardian presence and consent, i.e. signature. Such records shall be retained for a minimum of three (3) years from the date of service and available to the Division upon request. The Division and the body art establishment shall keep such records confidential.

7.0 Compliance Procedures

7.1 General

- 7.1.1 The establishment's valid permit shall be conspicuously displayed on the premises of the establishment for public view. Failure to display a valid permit shall be considered a violation of these Regulations.
- 7.1.2 A representative of the Division, upon presentation of proper identification and notice of intent to conduct an inspection, shall be permitted the right of access to an establishment to determine if the establishment is in compliance with these Regulations. The person in charge of the body art establishment shall allow the representative to inspect the establishment and shall provide to the representative information and records specified in these Regulations and to which the Division is entitled.
- 7.1.3 When an inspection reveals that the body art establishment is not in compliance with these Regulations, the permit holder shall take corrective action within the time specified by the Division. The permit holder may additionally be required to provide to the Division a written plan to correct violations of these Regulations, including the method of correction and the anticipated date of completion.

7.2 Grounds for Administrative Action

7.2.1 Operating without a permit

- 7.2.1.1 If a body art establishment is found operating without a valid permit, the Division shall order immediate closure. The closure shall be effective upon receipt of a written notice by the person in charge of the establishment. The establishment shall remain closed until proper application, submission and review of plans or inspection reveal compliance with these Regulations and approval for permit is made.
- 7.2.1.2 A conspicuous, colored placard obtained from the Division shall be prominently displayed at all entrances of a body art establishment which has failed to obtain a valid permit.

7.2.2 Imminent Health Hazard

- 7.2.2.1 Suspension of Permit. If conditions exist in a body art establishment that represent an imminent health hazard, the Division may suspend the operating permit without a hearing upon written notice for a period not to exceed ten (10) days. The suspension shall be effective upon receipt of written notice by the person in charge of the establishment. A suspension statement recorded on

the inspection report constitutes a written notice. The person in charge shall yield the permit to the Division.

7.2.2.2 Hearing. If the immediate health hazard is not eliminated, the Division shall schedule an administrative hearing within the ten (10) day period of suspension. The purpose of the hearing is to determine if the suspension should be extended, permit revoked or other action taken as necessary.

7.2.2.3 Reinstatement of Permit. The permit holder of the body art establishment may request, in writing, to the Division at any time during the suspension, an inspection for the purpose of showing that the imminent health hazard no longer exists. When the imminent health hazard no longer exists, the suspension shall be terminated and the permit returned. If the Division determines that the imminent health hazard has not been corrected and that the hazard still exists, the suspension remains in force pending a hearing, and the Division may recommend that the permit be revoked.

7.2.2.4 A conspicuous, colored placard obtained from the Division shall be prominently displayed at all entrances of a body art establishment whose permit stands suspended or revoked.

7.2.2.5 If operations are discontinued longer than sixty (60) days, or per order of the Division, the permit holder shall obtain approval from the Division before resuming operations.

7.2.3 Serious Violations, Repeat Violations and General Unsanitary Conditions

7.2.3.1 If serious or repeat violations of these Regulations occur, or if general unsanitary conditions exist, the Division may issue and properly serve due notice, by certified mail or by hand delivery, of the intention of the Division to suspend the permit of a body art establishment. The Division shall not suspend a permit of a body art establishment for serious or repeated violations which do not present an imminent health hazard, without having first issued and properly served such notice of intent to suspend. Within thirty (30) days of the date of such notice of intent to suspend, the permit holder may submit to the Division a written request for an administrative hearing. The suspension shall commence upon expiration of the notice of intent, unless within thirty (30) days of the date of such notice, the Division receives from the permit holder a written request for an administrative hearing. If the permit holder makes a timely request for an administrative hearing, the suspension shall be stayed pending the results of the hearing.

7.2.3.2 A conspicuous, colored placard obtained from the Division shall be prominently displayed at all entrances of a body art establishment whose permit stands suspended or revoked.

7.3 Administrative Hearing Procedures

7.3.1 Upon due notice that the Division intends to suspend the permit of a body art establishment, the permit holder may submit to the Division, within thirty (30) days of the date of such notice of intent, a written request for an administrative hearing.

7.3.2 After receipt of the request for administrative hearing, the Division shall schedule the hearing before an impartial hearing officer.

7.3.3 When an administrative hearing is scheduled, the permit holder of the establishment shall be informed at least (5) days prior to the hearing of the place, time, and date of the hearing and the specific charges against the establishment. Notification of the hearing shall be by certified mail or by hand delivery.

7.3.4 After hearing, the hearing officer shall issue a decision and provide the decision to the Division. Failure of the permit holder to be present for an administrative hearing shall result in automatic suspension of permit and recommendation for revocation.

7.3.5 A written report of the hearing decision shall be furnished by the Division to the permit holder of the body art establishment.

7.4 Penalty

7.4.1 Any person who neglects or fails to comply with the requirements of these Regulations may be subject to the provisions of 16 Del.C. §107, and may be subject to loss of their permit, be fined not less than \$100 and not more than \$1000, together with costs, or both, unless otherwise provided by law.

7.4.2 The Division may seek to enjoin violations of these Regulations.

5 DE Reg. 1713 (3/1/02)

15 DE Reg. 677 (11/01/11)

18 DE Reg. 645 (02/01/15) (Final)