

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #3

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**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

Division of Health

AGENCY: Department of Health and Human Resources TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §§ 16-37-4- & 16-1-4

AMENDMENT TO AN EXISTING RULE: YES _____ NO X

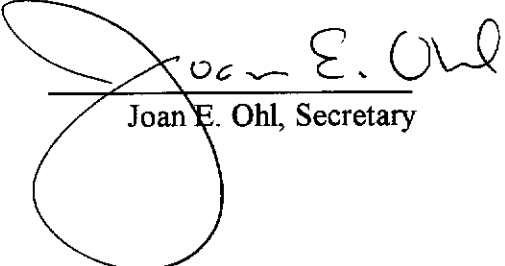
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 80

TITLE OF RULE BEING PROPOSED: Body Piercing Studio Business

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Joan E. Ohl, Secretary

9.60

Brief Summary of the Rule

This rule establishes the minimum standards for construction and operation of a Body Piercing Studio Business. It provides for the education and registration of those engaged in the body piercing business, provides for fees to cover the cost of plan review, permitting, inspection, registering, and the administration of a program to regulate body piercing. It mandates record keeping and establishes penalties for non-compliance.

Statement of Circumstances Which Require the Proposed Rule

This rule was mandated by the passage of W. Va. Code §16-37-1 et seq..

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Body Piercing Studio Business, 64 CSR 80

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: Division of Health
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule:

| | ANNUAL | | FISCAL YEAR | | |
|----------------------------------|----------|----------|-------------|------|------------|
| | Increase | Decrease | Current | Next | Thereafter |
| Estimated Total Cost | \$ | \$ | \$ | \$ | \$ |
| Personal Services | | | \$ | \$ | \$ |
| Current Expense | | | \$ | \$ | \$ |
| Repairs & Alterations | | | | | |
| Equipment | | | | | |
| Other | | | | | |
| Revenue | | | \$ | \$ | \$ |

2. Explanation of above estimates.

The rule will not have a fiscal impact on the Department of Health and Human Resources.

3. Objectives of this rule:

The rule establishes public health requirements for body piercing studio businesses and operators in West Virginia. The rule requires businesses to have an operating permit issued by the local health department.

Rule Title: Body Piercing Studio Business

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

The rule will enable local health departments to charge \$200 for a permit to operate a body piercing studio business. The fee is based upon the current permitting fee in place for tattoo parlors. The cost for conducting the inspections and processing the permits would be covered by the permit fee.

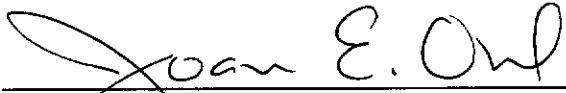
C. Economic Impact on Citizens/Public at Large.

The permit fee would add to the cost of doing business and in all likelihood would be passed on to the customer.

August 30, 2000

Date: _____

Signature of Agency Head or Authorized Representative:



Joan E. Ohl, Secretary
Department of Health and Human Resources

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: August 30, 2000

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Division of Health

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 243, Charleston, WV 25305

Telephone: (304) 558-5598

LEGISLATIVE RULE TITLE: Body Piercing Studio Business

1. Authorizing statute(s) citation: WV Code Sections 16-37-4 and 16-1-4

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
July 28, 2000

b. What other notice, including advertising, did you give of the hearing?

The proposed rule will be distributed to local health departments for their distribution to establishments engaged in the body piercing studio business and others.

A press release will also be distributed.

c. Date of Public Hearing(s) or Public Comment Period ended:
August 28, 2000

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X

No comments received _____

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

August 30, 2000

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule (please type):

Beth Marquart, Director

Regulatory Development/Department of Health and Human Resources

Building 3, Room 201, Capitol Complex

(304) 558-8933

Charleston, West Virginia 25305

(304) 558-6051 Fax

- g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule (please type):

Joseph Wyatt, Office of Environmental Health Services

815 Quarrier St., Suite 418

Charleston, West Virginia 25301-2616 (304) 558-2981

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefore?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

**TITLE 64
DIVISION OF HEALTH
LEGISLATIVE RULES**

**SERIES 80
BODY PIERCING STUDIO BUSINESS**

64CSR80

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TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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SECRETARY OF STATE

SERIES 80
BODY PIERCING STUDIO BUSINESS

§64-80-1. General.

1.1. Scope. -- This legislative rule establishes requirements regarding the business of body piercing. This rule should be read in conjunction with the provisions of W. Va. Code §16-37-1 et seq.

1.2. Authority. -- W. Va. Code §§16-37-4 and 16-1-4.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Applicability. -- This rule applies to any person who engages in the business of body piercing, or who proposes to do so, except as specified in Section 1.6 of this rule.

1.6. Exemptions. --

1.6.a. Health care providers licensed under Chapter 30 of the West Virginia Code; and

1.6.b. Persons who use a mechanized, pre-sterilized ear-piercing system that penetrates the outer perimeter or lobe of the ear.

1.7. Enforcement. -- This rule is enforced by the Director of the Division of Health.¹

§64-80-2. Definitions.

2.1. Adequate Ventilation. -- A free and unrestricted circulation of fresh air throughout the body piercing studio and the expulsion of foul or stagnant air.

¹The Department of Health and Human Resources (DHHR) was created by the Legislature's reorganization of the executive branch of State government in 1989. The Department of Health was renamed the Division of Health and made a part of the DHHR (W. Va. Code § 5F-1-1 et seq.). Administratively within the DHHR the Bureau for Public Health through its Commissioner carries out the public health function of the Division of Health.

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- 2.2. Antimicrobial Solution. -- A solution used to retard the growth of microorganisms.
- 2.3. Approved. -- A procedure of operation, installation or construction which is in accordance with the standards, specifications, and instructions established by the Division of Health.
- 2.4. Bloodborne Pathogens. -- Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).
- 2.5. Blood Exposure Incident. -- Piercing the skin through such events as needle sticks, cuts, and abrasions from material contaminated with blood from a client, or eye, mouth, other mucous membrane, or non-intact skin contact with blood or blood-contaminated material from a client.
- 2.6. Body Piercing. -- Puncturing the skin for the purpose of creating a hole to be decorated or adorned, but does not include the use of a mechanized, pre-sterilized ear-piercing system that penetrates the outer perimeter or lobe of the ear or both.
- 2.7. Body Piercing Studio. -- A room or space where body piercing is practiced or where the business of body piercing is conducted.
- 2.8. Body Piercer. -- A person who performs body piercing.
- 2.9. Contaminated. -- The presence or reasonably anticipated presence of blood, body fluids or other potentially infectious materials in or on the surface of an item.
- 2.10. Contaminated Waste. -- Material used in body piercing that requires disposal.
- 2.11. Director. -- The Director of the Division of Health or his or her designee.
- 2.12. Exposure Control Plan. -- A written plan of procedures for those who perform body piercing in a facility on how to implement the requirements of this rule, and that eliminates or minimizes employee and client exposure to bloodborne pathogens and other communicable diseases.
- 2.13. Facility. -- A room, shop, space or vehicle where body piercing is performed.
- 2.14. Instrument. -- Body piercing equipment that includes, but is not limited to needles, needle bars, needle tubes, forceps, hemostats, tweezers, pliers, or other implements used to pierce, or be inserted into any part of the human body for the intended purpose of making a

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permanent hole. Such equipment also includes studs, hoops, rings, and other decorative jewelry, materials or apparatuses inserted into any part of the body for the intended purpose of placement in a hole resulting from piercing.

2.15. Minor. -- Any person under the age of 18 (eighteen) years.

2.16. Operator. -- Any person who operates, controls or manages a body piercing studio, and whose studio has been issued an operating permit by the local board of health.

2.17. Owner. -- A person that owns, controls or has custody of a place of business where body piercing is performed.

2.18. Permanent Hole. -- A hole produced by piercing or puncturing any part of the body with instruments intended to leave an opening in body tissue(s) into which an appropriate device may be inserted. Permanent hole would include any body part newly pierced which is undergoing a healing process and any piercing whether removal of a device from the perforation would result in healing of the tissue or not.

2.19. Permit. -- A written document issued by the Director giving a person permission to operate a body piercing studio business.

2.20. Piercing Device. -- A device used for the creation of an opening in the human body for the purpose of inserting jewelry or other decoration .

2.21. Piercing Gun. -- A handheld tool that shall be used exclusively for piercing the ear, into which single use pre-sterilized studs and clutches are placed and inserted into the ear by hand squeezed or spring loaded action to create a permanent hole. The tool must be made of plastic, stainless steel or other material that allows disinfection.

2.22. Procedure Area. -- The immediate area where instruments and supplies are placed during a procedure.

2.23. Purchased pre-sterilized. -- Instruments or procedure setups that are sold individually packaged and sterilized. Each package shall have an auditable sterilization lot number from a sterilization facility.

2.24. Sanitization. -- The effective bactericidal and virucidal treatment of clean equipment surfaces by a process that has been approved by the Director as being effective in destroying pathogens and different than sterilization.

2.25. Single Use. -- Products, instruments or items that are used one time on one client and then properly disposed of in accordance with 64 CSR 56, WV Infectious Medical Waste Rule”.

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2.26. Standard Precautions. -- All blood and body fluids are treated so as to contain all blood-borne pathogens and all proper precautions are taken to prevent the spread of any blood-borne pathogens.

2.27. Technician. -- An individual who engages in the practice of body piercing.

2.28. Sterilization. -- The destruction of all living organisms including spores.

2.29. Workstation. -- An area such as a separate room or a screened area, that is set up to perform body piercing to insure privacy when performing nipple, genital or other discretionary piercing.

§64-80-3. Plan Review, Permits, Hearings, Notices and Orders.

3.1. Plan Review.

3.1.a. When a Body Piercing Studio Business opens or is extensively remodeled, and when an existing structure is converted to use as a Body Piercing Studio Business, the owner or operator shall submit plans and specifications for the construction, remodeling, or conversion of the business to the Director for review and approval at least forty-five (45) days before beginning.

3.1.b. Once the completed plans are received by the Director, the Director shall review them within forty-five (45) days.

3.2. Permit to operate.

3.2.a. On or after July 1, 2001, no person shall operate a Body Piercing Studio Business who does not possess a valid permit issued to him or her by the Director.

3.2.b. To apply for a permit to operate a Body Piercing Studio Business, a person shall submit a completed, written application along with a non-refundable fee of two hundred dollars (\$200.00) to the Director on a form obtained from the Director.

3.2.c. The applicant shall submit to the Director an application for a permit at least fifteen (15) days before the beginning of operations.

3.2.d. Prior to approving the application for a permit, the Director shall inspect the proposed facility to determine compliance with this rule. Only persons who comply with the applicable provisions of this rule will be issued a permit.

3.2.e. A Body Piercing Studio Business in operation at the time this rule becomes effective shall meet all applicable requirements of this rule.

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3.2.f. Permits are not transferable or assignable and automatically become invalid upon a change of ownership of the facility, or upon suspension or revocation of the permit.

3.2.g. A permit to operate expires at midnight on the 30th day of June following the date of issuance.

3.2.h. The applicant shall submit to the Director an application for the renewal of a permit at least fifteen (15) days prior to the expiration date of the existing permit.

3.2.i. In the event of an intended change or an actual change in ownership of a facility, an applicant shall submit an application for a permit to operate to the Director at least fifteen (15) days before the proposed or actual change is effected.

3.2.j. The Director may suspend or revoke a permit if he or she finds that the facility is being maintained or operated in violation of this rule.

3.2.k. The Director may revoke a permit to operate for repeated or serious violations of any of the requirements of this rule or for interference with the Director in the performance of his or her duties.

3.2.l. The Director shall not reinstate a permit to operate until he or she determines by an inspection that the facility is in compliance with all applicable provisions of this rule and any orders, rules or instructions issued by the Director.

3.2.m. The operator shall post the operational permit required in §64-80-3.2.a. and the health department public notice in §64-80A in a conspicuous place within the facility, and the permit shall be readily available to the Director.

3.2.n. The permit to operate a Body Piercing Studio business must be posted in a conspicuous location visible to the public beside the Health Department public notice.

3.3. Hearings, Notices and Orders.

3.3.a. When the Director makes an inspection of a facility and discovers that any of the provisions of this rule have been violated, he or she shall notify the operator of the violations by means of an inspection report form or other written notice. The operator shall correct the violations within the time specified in the notice.

3.3.b. When the Director finds that any facility governed by this rule constitutes an imminent hazard to public health, he or she may, without notice or hearing, issue a written order to the operator or person in charge citing the existence of the condition and requiring action to be taken to remedy the condition, including the immediate suspension of the permit to operate.

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3.3.b.1. Any person to whom the order is directed shall comply with the order immediately, but upon written petition to the Director shall be afforded a hearing on the matter as set forth in subdivision 3.3.c. of this rule.

3.3.c. A person whose application for a permit to operate a facility governed by this rule has been denied, or whose permit has been suspended or revoked, may submit a written petition to the Director requesting a hearing on the matter. The Director shall grant a hearing on the matter within ten (10) days after he or she has received the written petition.

3.3.d. The filing of a petition for a hearing on a permit denial, suspension, or revocation shall not stay or suspend the execution of the notice or order resulting in the permit denial, suspension, or revocation.

§64-80-4. Inspections.

4.1. The Director is charged with the enforcement of all provisions of these standards, and all standards adopted pursuant to it. The Director may enter, inspect, impound, copy records, and secure any samples, photographs, or other evidence from any body piercing shop, or any facility suspected of being a body piercing shop, for the purpose of enforcing these standards.

4.2. The Director shall inspect a facility governed by this rule at least once a year.

4.3. The Director shall also make additional inspections as necessary to determine satisfactory compliance with the provisions of this rule or any orders, notices, instructions or specifications issued pursuant to this rule.

4.4. The Director shall discuss the inspection report with the person in charge at the time of inspection.

4.5. Facility Owner Responsibilities.

4.5.a. The facility owner or operator of any body piercing facility shall:

4.5.a.1. Allow the Director or his or her designee to enter any body piercing shop within his or her jurisdiction during business hours to inspect, and make as many additional inspections or re-inspections as are necessary for the enforcement of these standards;

4.5.a.2. Be responsible for all facility technicians complying with all health, safety, sanitation and sterilization rules and standards of the Director;

4.5.a.3. Maintain a list of technicians providing services at the facility for review by the Director during inspections; and

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4.5.a.4. Develop and ensure compliance with the Exposure Control Plan as specified in Section 13. A copy of the plan must be available at all times for use and inspection.

§64-80-5. Facility Requirements.

5.1. All floors, walls and ceilings shall be made of smooth nonabsorbent and nonporous material that are easily cleanable. Concrete blocks or other masonry used in wall construction shall be covered or made smooth and sealed for a washable surface.

5.2. Adequate toilet facilities shall be provided in accordance with the specifications of the BOCA National Plumbing Code as specified by the West Virginia State Fire Commission. Hand sink must be located inside the restroom facility and shall be supplied with liquid hand cleanser and single use paper towels or other approved hand-drying device.

5.3. The premises shall be constructed and maintained in a state of good repair at all times to prevent insect and rodent infestation.

5.4. Body piercing activities shall be separated from any other activities by a solid wall.

5.5. The establishment shall be well ventilated and be provided with an artificial light source equivalent to at least twenty (20) foot-candles.

5.6. At least fifty (50) foot-candles of artificial light shall be provided at the level where the body piercing procedure is being performed.

5.7. All surfaces, including but not limited to, counters, tables, equipment, chairs, recliners, shelving, cabinets in the service areas and cleaning room shall be made of smooth, non-absorbent, non-porous materials to allow for easy cleaning.

5.8. Hand sinks with hot and cold running water operated by wrist or knee action shall be located in each work area. Hand sinks shall be supplied with liquid soap and single-use paper towels from sanitary dispensers. If there are two or more work stations within a room, all may share the hand sink. A work station in a separate room shall include a hand sink.

5.9. The cleaning room or area shall have a separate sink reserved for instrument clean up activities only.

5.10. Water supply shall be from an approved source.

5.11. Sewage including liquid wastes shall be disposed of in a public sewer or, in absence thereof, in a manner approved by the Director.

§64-80-6. Temporary and Mobile Facilities.

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6.1. Temporary facilities include those for educational or convention purposes. To the extent possible, they shall meet the facility requirements in Section 10. At a minimum, they must include:

6.1.a. Temporary handwash facilities and hand sanitizer located within each work or demonstration area. A temporary handwash facility shall consist of liquid hand cleanser, single-use paper towels and warm potable water dispensed from an insulated container with a spigot that is raised a minimum of twenty-five (25) inches off the floor. Wastewater shall be collected in a bucket placed on the floor under the spigot. Warm potable water shall be replenished and wastewater removed as necessary.

6.1.b. At least fifty (50) foot-candles of light at the level where the procedure is being performed.

6.1.c. A separate cleaning and sterilization area must be provided for use by the participants that supplies an adequate number of sinks and Director approved sterilization units for cleaning and sterilizing equipment to be used during the event.

6.1.d. Only sterilization units approved by the Director and used, cleaned and maintained according to manufacturer's instructions shall be utilized. All sterilization units used at the event shall have certification of a negative spore test on the sterilizer within the last 30 days.

6.2. Mobile units or vehicles must comply with the following requirements.

6.2.a. The mobile vehicle shall be equipped with a sink for the exclusive use of the technicians for hand washing and preparing customers. An adequate supply of potable water shall be maintained at all times that the mobile shop is open for business.

6.2.b. All liquid wastes shall be stored in an adequate storage tank with a capacity at least fifty percent (50%) greater than the capacity of the on-board potable water. Liquid wastes shall be disposed of at any approved trailer wastewater disposal site.

6.2.c. If there is not an on-board rest room, the mobile vehicle shall be operated within 200 feet of a public restroom

6.2.d. All procedures must be performed inside the mobile vehicle. No procedures shall be performed outside of the vehicle.

§64-80-7. Housekeeping Standards.

7.1. All body piercing facilities shall meet the following criteria:

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7.1.a. All areas shall be kept neat, clean and in good repair.

7.1.b. All surfaces and equipment (chairs, work stations, counters, client recliners or chairs, dispensers) in the procedure area shall be made of smooth, non absorbent, non-porous material that can withstand repeated disinfection.

7.1.c. An Environmental Protection Agency (EPA) registered disinfectant or germicide (iodophor, phenolic, or alcohol containing germicide, or a 1:100 dilution of 5.25% household bleach and water which equals two (2) tablespoons of bleach in one (1) quart of water) shall be used after cleaning to disinfect any surface contaminated with blood or body fluids.

7.1.d. All facilities shall have the waiting area separated from the workstations and the cleaning room or area. A public restroom shall be available to clients during all business hours.

7.1.e. The cleaning room or area shall be set up in a manner to provide distinct, separate areas for cleaning equipment, and for the handling and storage of sterilized equipment. The cleaning area sink shall be reserved for instrument cleaning only and shall not be used as a janitorial sink.

7.1.f. Large capacity ultrasonic cleaning units shall be clearly labeled biohazardous and placed away from the sterilizer and workstations. All ultrasonic cleaners shall be cleaned and maintained according to manufacturer's specifications.

7.1.g. Adequate foot-operated receptacles shall be provided in each workstation for disposal of trash and debris.

7.1.h. Each work station shall have a Director approved sharps container that is rigid, puncture proof, leak proof and red in color for disposal of sharp objects that come into contact with blood or body fluids.

7.1.i. The procedure area and client chair/table must be wiped down with an EPA registered disinfectant or germicide using a single-use paper towel before and after serving each client.

7.1.j. All germicides and disinfectants must be used according to manufacturer's recommendations.

7.1.k. All chemicals shall be properly labeled and stored.

7.1.l. Pets or other animals shall not be permitted in the facility. Trained guide or assistance animals for the disabled and fish in aquariums in the waiting area are exempted.

§64-80-8. Exposure Control Plan.

8.1. The owner of every body piercing facility shall establish a written Exposure Control Plan applying to all those who perform body piercing within a facility, describing how the applicable requirements of this standard will be implemented. This plan shall be made available to the Director during any inspection. The Exposure Control Plan shall contain at least the method of implementation for each of the following applicable sections of these standards:

- 8.1.a. §64-80-13. Clients;
- 8.1.b. §64-80-5. Facility Requirements;
- 8.1.c. §64-80-7. Housekeeping Standards;
- 8.1.d. §64-80-10. Approved Sterilization Equipment and Monitoring Methods;
- 8.1.e. §64-80-11. Instrument Sterilization and Set-Up;
- 8.1.f. §64-80-12. Contaminated Wastes; and
- 8.1.g. §64-80-14. Body Piercing.

§64-80-9. Exposure Control Training Requirements.

9.1. All technicians must receive exposure control training.

9.2. Training shall be completed within one year of the effective date of this standard and must be updated at least every three (3) years thereafter. Additional training must be completed when changes such as modification of procedures or institution of new procedures affect the practitioner's or client's exposure. The additional training may be limited to addressing the new exposures created.

9.3. Material appropriate in content and vocabulary to educational level, literacy, and language of trainees shall be used.

9.4. The training program shall contain, at a minimum, the following elements:

9.4.a. An accessible copy of the these and other applicable standards and an explanation of their contents;

9.4.b. A general explanation of the epidemiology and symptoms of blood borne diseases and other exposures appropriate for the practice of the trainee;

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9.4.c. An explanation of the modes of transmission of blood borne pathogens and other communicable diseases appropriate for the practice of the trainee;

9.4.d. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood for either the practitioner, the client, or both;

9.4.e. An explanation of the use and limitations of methods that will prevent or reduce exposure to both the practitioner and the client;

9.4.f. Information on the types, proper use, and removal, of gloves and proper hand washing techniques;

9.4.g. Information on hepatitis B vaccine, including information on its efficacy, safety, method of administration, and the benefits of being vaccinated;

9.4.h. An explanation of what constitutes a blood exposure incident, the risk of disease transmission following a blood exposure incident, and the options for post-exposure evaluation and follow-up if an exposure incident occurs, specific to each blood borne pathogen; and

9.4.i. An opportunity for interactive questions and answers with the person conducting the training session.

9.5. The person conducting the training shall be knowledgeable in the subject matter covered by the training program as it relates to the workplace that the training will address.

§64-80-10. Approved Sterilization Equipment and Monitoring Methods.

10.1. Instruments used in body piercing shall be properly cleaned and packaged in sterilizer bags with a color change indicator and then sterilized in a sterilizer that meets the following requirements:

10.1.a. Is sold as sterilizing equipment for medical instruments;

10.1.b. Has been approved by the Department;

10.1.c. Is used, cleaned and maintained to manufacturer's specifications; and

10.1.d. Is tested at least monthly (unless otherwise specified by manufacturer) by using a commercial biological monitoring system, utilizing *Bacillus stearothermophilus* spores, to assure that all microorganisms, including spores, have been destroyed. Biological indicator test results must be maintained for a period of three (3) years and made available for inspection at all times.

§64-80-11. Instrument Sterilization and Set-Up.

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11.1. Contaminated non-disposable equipment including needles, needle bars, needle tubes, needle caps, body piercing tubes or other instruments that are contaminated shall be immersed in liquid in the cleaning area or room until cleaned and sterilized.

11.2. Before being sterilized, all instruments shall be thoroughly cleaned in an ultrasonic cleaner following manufacturer's instructions.

11.3. After cleaning, non-disposable instruments shall be packaged into procedure set-ups with color change indicators or packaged individually in peel-packs with color change indicators. All packages shall be dated and initialed by the preparer. If a sterilized package has been breached or allowed to get wet, the instruments shall be re-packaged and re-sterilized before use.

11.4. After sterilization, the instruments shall be stored in a dry, clean cabinet or other tightly covered container reserved for storage of sterile instruments.

11.5. The facility shall retain the records of sterilization procedures for a minimum of at least the last three (3) years.

11.6. Wearing new clean disposable examination gloves, the body piercer shall use proper technique to assemble, without contamination, all instruments and supplies to be used in the procedure. All sterilized instruments shall remain in sterile packages until opened in front of the client. If a glove is pierced, torn or contaminated by contact with any non-clean surface, both gloves must be properly removed and discarded. The gloves shall be discarded after the completion of each procedure on an individual client, and hands shall be washed prior to donning the next pair of gloves. Under no circumstances shall a single pair of gloves be used on more than one person. The use of disposable examination gloves does not preclude or substitute for hand washing procedures as a part of a good personal hygiene program.

§64-80-12. Contaminated Wastes.

12.1. Contaminated wastes generated by a body piercing facility shall be managed in accordance with the West Virginia Infectious Medical Waste Rule, 64 CSR 56.

§64-80-13. Clients.

13.1. Persons under the age of eighteen (18) years may receive body piercing provided they are accompanied by their parent or guardian. The parent or guardian shall have valid picture identification. Nipple and genital piercing is prohibited on minors regardless of parental consent. Persons eighteen (18) years or older may receive body piercing without parental consent.

13.2. Body piercing shall not be performed on skin surfaces which have sunburn, rash, pimples, infection, open lesions, or manifest any evidence of unhealthful conditions.

64CSR80

13.3. Body piercing may not be performed on any person who is impaired by drugs or alcohol.

§64-80-14. Body Piercing Procedures.

14.1. Before beginning any body piercing procedure, the body piercer shall discuss the risks and responsibilities required in the particular piercing with the client, The client shall fill out and sign a client information form and the consent form for body piercing. One copy of each form shall be retained by the facility and the other copy shall be given to the client. The body piercer must also explain aftercare instructions and have the client initial the consent form to indicate that he or she has received written aftercare instructions.

14.2. The body piercer shall not smoke, eat or drink at the work station or cleaning room during or between procedures. The client may consume a pre-packaged beverage or snack.

14.3. The body piercer shall thoroughly wash hands and forearms with soap and warm water before and after serving each client, to prevent cross contamination and/or transmission of body fluids, infection or exposure to service related chemicals or wastes. Following thorough washing, the hands shall be dried using clean, single use paper towels.

14.4. The body piercer shall wear new clean disposable examination gloves for every client during the procedure. If a glove is pierced, torn or contaminated by coming into contact with any other person or non-clean surface, both gloves must be properly removed and discarded. Gloves shall be discarded after the completion of each procedure on an individual client, and hands shall be washed prior to donning a new pair of disposable examination gloves. Under no circumstances shall a single pair of gloves be used on more than one person. The use of disposable examination gloves does not preclude or substitute for hand washing procedures as part of a good personal hygiene program.

14.5. The body piercer shall use freshly laundered linens or new disposable dental bibs or drapes for each client. All drapes, dental bibs, and linens shall be stored in a closed cabinet or container. Used disposable items shall be placed into a closed container that is lined with a plastic bag for disposal at the end of the day. Used linens shall be placed into a laundry hamper lined with a plastic bag.

14.6. All body piercing needles shall be single use, sterilized disposable piercing needles slightly larger or of the same gauge as the jewelry or ornaments to be inserted, and disposed of immediately after use in a sharps container.

14.7. All instruments, as defined in Section 2, shall be properly cleaned and sterilized in individual bags with color indicator strips. Each bag shall be dated and initialed by the person preparing the instruments. Sterilizers shall be approved by the Director.

64CSR80

14.8. All non-sterilizable implements such as calipers shall be nonporous and disinfected after each use with an appropriate disinfectant.

14.9. Only pre-sterilized jewelry or ornaments in new or good condition shall be used for piercing. Ear studs or other jewelry designed for ears shall not be used in other parts of the body.

14.10. Only jewelry made of implant grade, ASTM and ISO 5832-1 implant grade stainless steel, solid 14K through 24K gold, niobium, titanium, platinum or other materials approved by the Director shall be used in newly pierced skin.

14.11. Immediately, before the procedure is begun, the procedure area shall be wiped down with an EPA registered germicide or disinfectant or a solution of two (2) tablespoons of five and one quarter percent (5 1/4 %) available chlorine bleach in one (1) quart of water and the procedure area covered with an uncontaminated paper towel or tray cover. All instruments and supplies needed for the procedure shall then be arranged on the paper.

14.12. Before piercing, the immediate and surrounding area of the skin which is to be pierced shall be washed with an EPA-approved antiseptic solution applied with a clean, single-use paper product. 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 sterilized in an autoclave after each use. Following shaving, the skin and surrounding area shall be washed with an EPA-approved antiseptic solution applied with a clean single-use paper product.

14.13. Upon completion of the piercing, the body piercer shall review verbal and printed instructions to the client on the care of the body opening created by the piercing to minimize the likelihood of infection. Aftercare instructions shall specify:

14.13.a. Care specific to the site of the piercing;

14.13.b. Information regarding tightness to prevent accidental ingestion or imbedding of certain jewelry if appropriate;

14.13.c. Restrictions;

14.13.d. Signs and symptoms of infection; and

14.13.e. Instructions to consult a physician if infection occurs.

§64-80-15. **Records.**

15.1. Every Body Piercing Studio Business shall keep a record of all body piercing procedures performed for a period of three (3) years. The record shall include:

64CSR80

- 15.1.a. The client's name;
 - 15.1.b. Date of birth;
 - 15.1.c. Client's address;
 - 15.1.d. Date of the procedure;
 - 15.1.e. Type and location of each procedure performed;
 - 15.1.f. Name of the technician who performed each procedure;
 - 15.1.g. Signature of the client; and
 - 15.1.h. In the case of a minor, proof of parental or guardian presence and written consent.
- 15.2. Signed copies of the client Release Form and Aftercare Form shall be maintained by the establishment. These forms shall provide:
- 15.2.a. Verification that the client was given written and oral notification of the risks associated with body piercing; and
 - 15.2.b. Verification that the client was given written and oral instructions on post piercing skin care.
- 15.3. All records shall be available for inspection by the Director.

§16-29-16. Violations and penalties.

- 16.1. The penalty for violation of the provisions of this rule are established in W. Va. Code §16-37-5.

§64-80-17. Administrative Due Process.

- 17.1. Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

Public Notice 64-80A

Public Notice

Body Piercing Disclosure Statement

◆ **THE WEST VIRGINIA BUREAU FOR PUBLIC HEALTH AND YOUR LOCAL HEALTH DEPARTMENT DO NOT ENDORSE OR RECOMMEND BODY PIERCING IN ANY FORM.**

◆ **HEALTH DEPARTMENT PERMITS SIGNIFY SANITATION OF EQUIPMENT AND THE UTILIZATION OF PROPER PROCEDURES ONLY.**

As with any invasive procedure, body piercing may involve possible health risks. Body piercing could result in:

- ◆ Pain, bleeding, swelling, infection, scarring of the pierced area and nerve damage.

The Piercing Technician should:

- Properly cleanse the piercing site before piercing;
- Use sterilized equipment;
- Use sterile piercing techniques; and
- Inform the client of proper aftercare of the pierced area.

For complaints or comments please contact the Bureau for Public Health at (304) 558-2981, your local health department, or mail comments to 815 Quarrier Street, Suite 418, Charleston, WV 25301-2616.

PUBLIC COMMENTS AND RESPONSES

64 CSR 80

PUBLIC COMMENTS AND RESPONSES

Section 2 Definitions:

Comment # 1.2.16 Operator. - - any person who operates, controls or manages a body piercing studio, *and whose studio has been issued an operating permit by the local board of health.* This could cause problems because if they are operating without a permit, then they are not an "operator."

Answer # 1. Section 3.2.a. prohibits any person from operating a Body Piercing Studio Business who does not possess a valid permit issued to him or her by the Director. This should negate this concern.

Section 3: Plan Review, Permits, Hearings, Notices and Orders.

Comment # 2. The only concern I have is with section 3.2.n. that states that Body Piercing Studios operating in conjunction with permitted tattoo parlors are not required to pay an additional fee for a permit.

Comment # 3. We request that the portion of §64-80-3.2n. Relating to permit fee exemptions be stricken from the proposed rule prior to filing with the legislative rule making review committee.

Answer # 2 & 3. We agree. The exclusionary statement will be removed prior to filing.

Comment # 4. Fees do not cover expenses.

Answer # 4. The same fee that is used for tatoo facilities was used in the Body Piercing Studio Business Rule. The two operations are not that different and should cost about the same to administer.

Section 4 Inspections

Comment # 5. The concept of an occasional inspection being a guarantee or safeguard is a fallacy.

Answer # 5. The rule specifies a minimum of one inspection per year, not the maximum.

Comment # 6. Owner must require himself and employees to follow safe procedures.

Answer # 6. The requirements in Section 4.5 require the owner to comply with minimum standards and to insure that any employees comply with the minimum standards.

General Comments

Comment # 7. The effect on our youth will be to legitimize behavior that is indicative of psychological aberration. Children that are raised with weak personal identity and no standards will assume that since the piercing business is "legally permitted" by society the practice is acceptable, even encouraged.

Answer # 7. The Health Department does not approve body piercing in any form. This rule was promulgated to establish control over an activity which has a great potential to impact public health.

Comment # 8. I believe we are far away from our responsibilities with this body piercing business rule. I do not believe the rule should be promulgated.

Answer # 8. This rule was mandated by legislative action. It is now our business.

Agency Changes to

64 CSR 80

As a result of comments received

~~3.2.n. Body Piercing Studios operating in conjunction with tattoo parlors that are operating under a valid permit in compliance with Chapter 30, Article 33 are not required to pay an additional fee for a permit to operate a Body Piercing Studio business. The permit to operate a Body Piercing Studio business must be posted in a conspicuous location visible to the public beside the Health Department public notice.~~



Kanawha-Charleston Health Department

108 Lee Street E.
P.O. Box 927
Charleston, WV 25323



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AUG 22 2000

STAFF DEVELOPMENT
21

August 21, 2000

Beth Marquart, Director, Regulatory Support
Department of Health and Human Resources
Capitol Complex, Building 3, Room 201
Charleston, West Virginia 25305

Dear Ms. Marquart:

The purpose of this letter is to provide our comments on the proposed legislative rule 64CSR80, Body Piercing Studio Business. The Code of West Virginia, §16-37-4 et seq., requires the proposal of rules "... which shall provide at a minimum..... fees for permits and renewals of permits sufficient to cover the costs of inspecting facilities and administering this article....." However, the proposed rule expressly precludes the collection of an additional permit fee when the body piercing studio business is operated in conjunction with a permitted tattoo parlor (§64-80-3.2.n.) This provision of the proposed rule appears to directly conflict with the statute requiring said rule.

This provision might have been included as an innocent gesture of friendship toward individuals within the business community. However, it is clear that whoever drafted the rule was not familiar with what is required of those who will be responsible for conducting inspections or administering the program. This is clear from the fiscal note attached to the proposed rule which indicates that the Department of Health and Human Resources anticipates no fiscal impact from the proposed rule. On the contrary, local boards of health do anticipate a fiscal impact regardless of the location of the body piercing studio business and its operation either singularly or in conjunction with any other business. The administration of this program will require staff training, staff inspection and report completion time and various permit issuing and other clerical resource consumption. Therefore, the local boards of health will require a realistic fee to adequately reimburse these costs. Furthermore, it should be equitable for all establishments.

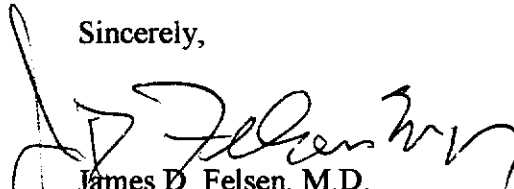
In this regard, it should be noted that there is no similar permit fee exemption for any other business operated in conjunction with a second business in a situation that requires a permit from the local board of health. This could be a dangerous precedent to set, ie. arbitrarily exempting one business but not others. Collectively, local boards of health could potentially lose thousands of dollars in revenue if fee exemptions became a requirement based upon the principles incorporated within this proposed rule.

Beth Marquart
August 21, 2000
Page 2

The Kanawha-Charleston Board of Health has admonished us on several occasions that because of direct funding limitations, we must assure that environmental health and other fees, to the extent possible, reflect the actual costs of providing any inspection and permitting service. The rule, as proposed, would significantly compromise our ability to comply with this instruction.

Therefore, we request that the portion of §64-80-3.2.n. relating to permit fee exemptions be stricken from the proposed rule prior to filing with the legislative rule making review committee. Thank you for your attention to this matter.

Sincerely,



James D. Felsen, M.D.
Medical Director

cc: Joe Wyatt

P. O. Box 129
Belmont, WV 26134

August 10, 2000

Beth Marquart, Director, Regulatory Support
Department of Health & Human Resources
Capitol Complex – Building 3, Room 201
Charleston WV 25305

Re: Comments on the Proposed Rule for a
Body Piercing Studio Business

Dear Ms. Marquart:

Fiscal Impact Comments

Paragraph 2.

There will be an, apparently, indirect impact to be considered. The impact will be on resources, time and work energy expended by the sanitarians to inspect these “businesses”. This expenditure will, at the least, take these intangibles away from other necessary programs. Body piercing is hardly a necessity.

Paragraph 4.b.

Presumably the term “covered” is used generally. The cost for all the services required to be performed is not covered. None of the health department fees get near to covering our expenses. If this were so, we would not see county health departments closing. Nor, hopefully, would we see the lowly sanitarian struggling to make it financially. It appears that many health departments believe they must pay their sanitarians at a level which allows that department to operate.

General Comments

The concept of an occasional inspection being a “guarantee” or a safe guard is a fallacy. The goal of inspections is to educate and encourage the owner-operator-manager to use that knowledge and interest. He must require himself or employees to follow safe procedures. Otherwise, anything is possible.

Persons who have their bodies pierced are not concerned with no pain or no infections. The reason to have a body piercing is to do something outrageous or bizarre. Pain and infection is nearly irrelevant. Are we going to regulate Xtreme Sports next to be sure their equipment is “approved” and “safe”?

In my former career as a sanitarian, I inspected one "tattoo parlor". The employee told me and another sanitarian that some of his customers came in "to get off on being hurt". Body piercing may be a form of prostitution.

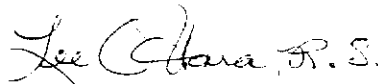
So what are we attempting to regulate here? Behavior. We have tried with great resource expenditure to treat the behavioral symptoms of drug addiction, as well as the trafficking of drugs. What have we accomplished?

I believe we are far away from our responsibilities with this body piercing business rule. The effect on our youth will be to legitimize behavior that is indicative of psychological aberration. Children that are raised with weak personal identity and no standards will assume that since the piercing business is "legally permitted" by society the practice is acceptable, even encouraged. This is a great disservice to the youth of West Virginia. What is next?

I ask that passage of this rule not be sought, and that it be deleted from the health department program.

~~We~~ We have often heard that morality cannot be legislated. Can immorality be legislated?

Sincerely,



Lee O'Hara, R.S.

C: Joseph Wyatt, OEHS
Legislative Rule Making Rev. Com.

64CSR80

permanent hole. Such equipment also includes studs, hoops, rings, and other decorative jewelry, materials or apparatuses inserted into any part of the body for the intended purpose of placement in a hole resulting from piercing.

2.15. Minor. -- Any person under the age of 18 (eighteen) years.

2.16. Operator. -- Any person who operates, controls or manages a body piercing studio, and whose studio has been issued an operating permit by the local board of health. *This could cause problems because if they are operating without a permit, then they are not an "operator"*

2.17. Owner. -- A person that owns, controls or has custody of a place of business where body piercing is performed.

2.18. Permanent Hole. -- A hole produced by piercing or puncturing any part of the body with instruments intended to leave an opening in body tissue(s) into which an appropriate device may be inserted. Permanent hole would include any body part newly pierced which is undergoing a healing process and any piercing whether removal of a device from the perforation would result in healing of the tissue or not.

2.19. Permit. -- A written document issued by the Director giving a person permission to operate a body piercing studio business.

2.20. Piercing Device. -- A device used for the creation of an opening in the human body for the purpose of inserting jewelry or other decoration.

2.21. Piercing Gun. -- A handheld tool that shall be used exclusively for piercing the ear, into which single use pre-sterilized studs and clutches are placed and inserted into the ear by hand squeezed or spring loaded action to create a permanent hole. The tool must be made of plastic, stainless steel or other material that allows disinfection.

2.22. Procedure Area. -- The immediate area where instruments and supplies are placed during a procedure.

2.23. Purchased pre-sterilized. -- Instruments or procedure setups that are sold individually packaged and sterilized. Each package shall have an auditable sterilization lot number from a sterilization facility.

2.24. Sanitization. -- The effective bactericidal and virucidal treatment of clean equipment surfaces by a process that has been approved by the Director as being effective in destroying pathogens and different than sterilization.

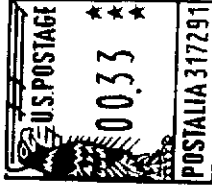
2.25. Single Use. -- Products, instruments or items that are used one time on one client and then properly disposed of in accordance with 64 CSR 56, WV Infectious Medical Waste Rule".

Nicholas County Health Department

Public Health

1 Stevens Road

Summersville, West Virginia 26651



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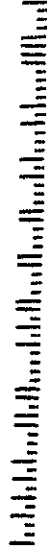
Beth Marquart, Reg. Support

DHHR

Capitol Complex - Bldg 3, Rm 201

Charleston, W 25305

25305/0003



This is my point!
 Please add to
 my comments.
 Sandra L O'Hara

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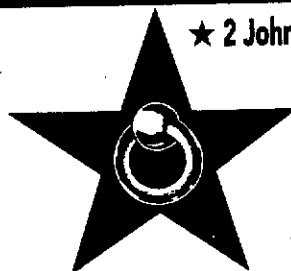
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Beth Margaret Di Rogio,
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