



RE: Rules 4731-17-01 through 4731-17-07 (Universal Precautions Rules)

Rules 4731-17-01 through 4731-17-07, Ohio Administrative Code, regarding universal precautions, are attached for your review. The Medical Board is seeking interested party input on proposed changes to the rules as outlined below.

- Rule 4731-17-01:** Definitions: Proposed addition of cosmetic procedures such as Botox injections, dermal fillers, permanent makeup, hair replacement and tattoos to the definition of “invasive procedure”.
- Rule 4731-17-02:** Universal Precautions: Addition of hepatitis C virus as one of the diseases listed in the rule.
- Rule 4731-17-03:** Hand washing: No changes proposed.
- Rule 4731-17-04:** Disinfection and sterilization: Clarification that reusable equipment is classified by the FDA as reusable; spelling corrections for the words, “sterilization” and “aluminum.”
- Rule 4731-17-05:** Handling and Disposal of Sharps and Wastes: No changes proposed.
- Rule 4731-17-06:** Barrier Techniques: No changes proposed.
- Rule 4731-17-07:** Violations: Add oriental medicine practitioners to paragraph (C) regarding acupuncturists.

The rules in Chapter 4731-17 are also applicable to physician assistants via Rule 4730-1-07, Ohio Administrative Code.

Deadline for submitting comments: **January 14, 2016**

Comments to: Sallie Debolt, Senior Counsel
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4731-17-01 Definitions.

For purposes of this chapter of the Administrative Code:

- (A) "Licensee" means any person holding or practicing pursuant to a certificate issued by the board under Chapter 4730., 4731., 4760., 4762., or 4774. of the Revised Code.
- (B) "Invasive procedure" means any of the following:
 - (1) Surgical or procedural entry into tissues, cavities, or organs or repair of major traumatic injuries associated with any of the following: an operating or delivery room, emergency department, or outpatient setting, including physicians' offices; cardiac catheterization and angiographic procedures; a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists.
 - (2) Any entry into the hair follicle using an electric modality for the purpose of hair removal.
 - (3) The practice of acupuncture as defined in section 4762.01 of the Revised Code.
 - (4) The performance of fluoroscopic procedures pursuant to section 4774.08 of the Revised Code.
 - (5) THE PERFORMANCE OF COSMETIC PROCEDURES, SUCH AS THE INJECTION OF BOTULINUM TOXIN, DERMAL FILLERS, PERMANENT MAKEUP, LASER HAIR REMOVAL, AND HAIR REPLACEMENT PROCEDURES.
- (C) "FDA" means the United States food and drug administration.
- (D) "EPA" means the United States environmental protection agency.

4731-17-02 Universal precautions.

Licensees who perform or participate in invasive procedures shall, in the performance of or participation in any such procedures or functions, be familiar with, observe and rigorously adhere to the acceptable and prevailing standards for universal blood and body fluid precautions to minimize the risk of being exposed to or exposing others to the hepatitis B virus (HBV), THE HEPATITIS C VIRUS (HCV), and THE human immunodeficiency virus (HIV). The acceptable and prevailing universal blood and body fluid precautions which the licensee follows shall include at least the following:

- (A) Appropriate use of hand washing;
- (B) Effective disinfection and sterilization of equipment;
- (C) Safe handling and disposal of needles and other sharp instruments; and
- (D) Appropriate barrier techniques including wearing and disposal of gloves and other protective garments and devices.

4731-17-03 Hand washing.

Licensees who perform or participate in invasive procedures shall follow acceptable and prevailing standards for hand washing which shall include at least the following:

- (A) Hands shall be washed appropriately prior to performing or participating in an invasive procedure and after performing or participating in an invasive procedure;
- (B) Hands and other skin surfaces shall be washed immediately and thoroughly if contaminated with blood or other body fluids; and
- (C) Hands shall be washed immediately after gloves are removed.

4731-17-04 Disinfection and sterilization.

Instruments and other reusable equipment CLASSIFIED BY THE FDA AS REUSABLE, used by licensees who perform or participate in invasive procedures shall be appropriately disinfected and sterilized according to acceptable and prevailing standards for disinfection and sterilization which shall include at least the following:

- (A) Instruments and devices that enter the patient's vascular system or other normally sterile areas of the body shall be sterilized before being used for each patient;
- (B) Instruments and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces shall be sterilized when possible, or undergo high-level disinfection if they cannot be sterilized before using for each patient;
- (C) Instruments and devices that are able to withstand repeated exposure to heat shall be heat sterilized. Sterilization shall be accomplished by autoclave, dry heat, unsaturated chemical vapor, ethylene oxide, HYDROGEN PEROXIDE GAS PLASMA, or any other FDA/EPA-approved method;
- (D) Instruments and items that cannot withstand heat sterilization shall be subjected to a high level disinfection process;
- (E) Heat sterilizing devices shall be tested for proper function on a weekly basis by means of a biological monitoring system that indicates microorganism kill. Documentation shall be maintained either in the form of a log reflecting dates and person(s) conducting the testing or copies of reports from an independent testing entity. The documentation shall be maintained for a period of at least two years. In the event of a positive biological spore test, the licensee must take immediate remedial action to ensure that heat sterilization is being accomplished;
- (F) Surface disinfection:
 - (1) Environmental surfaces that are contaminated by blood or other body fluids shall be disinfected with a chemical germicide that is registered with the environmental protection agency as a "hospital disinfectant" or sodium hypochlorite and is mycobactericidal at use-dilution. The disinfection process shall be followed before each patient, AND
 - (2) Impervious backed paper, aluminum foil or plastic wrap shall be used to cover surfaces that may be contaminated by blood or other body fluids and that are difficult or impossible to disinfect. The cover shall be removed, discarded and then replaced between patients, ~~and~~
- (G) Single use items used in treating a patient, which have become contaminated by blood or other body fluids, shall be discarded and not reused. Unless sterilized and reused in accordance with current guidelines established by the FDA. Single use items being

reused in treating a patient shall be adequately cleaned and sterilized. Single use items shall not be reused if the items' physical characteristics and quality have been adversely affected or if the items are incapable of being reused safely and effectively for their intended use.

4731-17-05 Handling and disposal of sharps and wastes.

- (A) To prevent injuries, no licensee performing or participating in invasive procedures shall recap needles, or purposely bend or break needles or other sharp instruments or items by hand.
- (B) After a licensee who is performing or participating in an invasive procedure uses disposable needles, syringes, scalpel blades or other sharp items, the licensee shall place the disposable sharp items used in a puncture-resistant container for disposal. The puncture-resistant container shall be located as close a practicable to the use area.
- (C) All sharp items and contaminated wastes shall be disposed of according to requirements established by federal, local and state environmental or regulatory agencies.

4731-17-06 Barrier techniques.

All licensees who perform or participate in invasive procedures shall routinely use appropriate barrier precautions to prevent skin and mucous-membrane contact with blood and other body fluids of all patients. The barrier techniques to be followed are:

- (A) All licensees shall wear disposable gloves when performing or participating in invasive procedures. Hands shall be washed when gloves are removed. Before performing or participating in invasive procedures on another patient, the licensee shall wash hands and reglove with another pair of disposable gloves. If a glove is torn or a needlestick or other injury occurs, the glove shall be removed and a new glove used as promptly as patient safety permits. The needle or instrument involved in the incident shall be removed from the sterile field. Disposable gloves shall not be washed or reused for any purpose.
- (B) All licensees shall wear masks and protective eyewear when performing or participating in invasive procedures if during the procedure there is likely to be spattering or splashing of blood or other body fluids.
- (C) Gowns or aprons made of materials that provide an effective barrier shall be worn by all licensees who are performing or participating in invasive procedures if during the procedure there is likely to be spattering or splashing of blood or other body fluids.

4731-17-07 Violations.

- (A) A physician assistant who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(19) and (B)(21) of section 4730.25 of the Revised Code.
- (B) An anesthesiologist assistant who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(4) and (B)(19) of section 4760.13 of the Revised Code.
- (C) An acupuncturist OR ORIENTAL MEDICINE PRACTITIONER who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(4) and (B)(20) of section 4762.13 of the Revised Code.
- (D) A radiologist assistant who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(4), and (B)(19) of section 4774.13 of the Revised Code.
- (E) Any other licensee who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(6), (B)(20) and (B)(29) of section 4731.22 of the Revised Code.