

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Chapters 4731-17 and 4731-19

Rule Number(s): 4731-17-01, 4731-17-02, 4731-17-03, 4731-17-04, 4731-17-05, 4731-17-06,

4731-17-07, 4731-19-01, 4731-19-02, 4731-19-03, 4731-19-04, 4731-19-05, 4731-19-06, and

4731-19-07

Date: \_\_\_\_\_

**Rule Type:**

New

5-Year Review

Amended

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

**Regulatory Intent**

1. Please briefly describe the draft regulation in plain language.

*Please include the key provisions of the regulation as well as any proposed amendments.*

The rules in Chapter 4731-17, OAC, reflect the mandate of Section 4731.051, ORC, for the Medical Board to adopt rules to establish universal blood and fluid precautions to be used by each licensee who performs exposure prone invasive procedures.

The rules in Chapter 4731-19, OAC, were adopted to reflect societal concerns about patient exposure when a health care worker is diagnosed with HIV or HBV. In 1991, The Centers for Disease Control and Prevention adopted Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients during Exposure-Prone Invasive Procedures. The guidelines recommended that infected health care workers not perform exposure-prone procedures unless they have sought counsel from an expert panel and that prospective patients are notified of the health care worker's seropositivity prior to undergoing an exposure-prone procedure. Later in 1991, Congress adopted a law requiring states to adopt the CDC guidelines or adopt similar guidelines for their state. (Section 633 of Public Law 102-141). The Ohio Department of Health adopted guidelines in 1992. The Medical Board adopted Rules 4731-19-01 through 4731-19-07, Ohio Administrative Code in 1996. All of the rules in Chapter 4731-19 are proposed to be rescinded.

**2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**

The rules in Chapter 4731-17 are authorized by Sections 4730.07, 4731.05, 4731.051, 4760.19, 4762.19, and 4774.11, ORC.

The rules in Chapter 4731-19 were authorized by Sections 4730.07, 4731.05, 4731.051, 4760.19, 4762.19, and 4774.11.

**3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.**

The rules in Chapter 4731-17 do not implement a federal requirement.

The rules in Chapter 4731-19 implemented the guidelines adopted by the Ohio Department of Health in response to Section 633 of Public Law 102-141.

**4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

As to the rules in Chapter 4731-19, the CDC no longer has relevant guidelines.

**5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The purpose of the rules in Chapter 4731-17 is to protect the public and health care workers from bloodborne pathogens and pathogens that may be transferred via other bodily fluids.

The purpose of the rules in Chapter 4731-19 was to protect patients from exposure to specific bloodborne pathogens. Please note that the rules in Chapter 4731-19 are proposed to be rescinded.

**6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the rules in Chapter 4731-17 will be measured by the number of disciplinary actions the Medical Board takes for failure to utilize the required universal precautions.

The rule in Chapter 4731-19 are proposed to be rescinded.

**Development of the Regulation**

**7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

For the rules in Chapter 4731-17, on June 11, 2015, Medical Board staff met with a representative of the Cosmetic Therapy Association to discuss, among other things, the need to implement universal precautions in cosmetic therapy practice.

For the rules in Chapter 4731-19, during 2014 the Medical Board staff had preliminary discussions with Ohio Department of Health staff concerning the rules in Chapter 4731-19, with periodic discussions continuing throughout 2015. In early 2015, the Medical Board contacted the Ohio Hospital Association to discuss concerns about the rules. The discussions with OHA staff occurred periodically throughout the year.

In addition to the above, on December 11, 2015, the rules in Chapters 4731-17 and 4731-19 were sent to such organizations as: Ohio State Medical Association, Ohio Osteopathic Medical Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland and Northern Ohio, all county and city medical associations, Ohio Hospital Association, Ohio Department of Health, Ohio Association of Physician Assistants, attorneys who represent respondents before the Medical Board, and other individuals and groups who receive notice of all Medical Board rules activities.

**8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

For the rules in Chapter 4731-17, the input from the Cosmetic Therapy Association was that there needs to be additional emphasis on universal precautions for cosmetic therapists. Cosmetic therapists perform electrolysis and laser hair removal. Rule 4371-01 is amended by adding language to include the performance of cosmetic procedures such as laser hair removal under the definition of an “invasive procedure” in order to clarify that the rules are applicable to those services.

For the rules in Chapter 4731-19, the Ohio Department of Health first contacted the Medical Board with a request that the rules be amended to remove the provisions that refer Medical Board licensees with HIV or HBV to that agency for monitoring. The Department of Health no longer provides such monitoring services. Currently, 26 individuals are under the Board's confidential monitoring program.

Medical Board staff then conducted research to determine how other state medical boards oversee licensees with HIV or HBV. It was discovered that the Occupational Health and Safety Administration (OSHA) revised its Bloodborne Pathogens standard to require the use of engineering and work practice controls to eliminate or minimize employee exposure. Medical Board staff then talked with Ohio Hospital Association staff members concerning the hospital practices for monitoring infected health care providers. It was learned that concerns are addressed through universal precaution practices. The Centers for Disease Prevention and Control also has guidelines for universal precautions.

In summary, the Ohio Department of Health and local health departments no longer take reports or provide monitoring to licensees infected with HIV or HBV. The Ohio Department of Health no longer approves institutional review panels. Hospitals have voluntary testing processes and when an employee discloses HIV, HBV or HCV status, an expert review panel assesses patient risk based upon the employee's virus load and the job duties of the employee. Based upon these findings, the Medical Board proposes to rescind the rules in Chapter 4371-19.

**9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

The rules in Chapter 4731-17 are compatible with the CDC and OSHA guidelines.

As discussed in Item #8, the Medical Board's proposal to rescind the rules in Chapter 4731-19 is based upon information from the CDC, Ohio Department of Health, OSHA, and the Ohio Hospital Association.

**10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

The Medical Board did not consider alternative regulations instead of amending the rules in Chapter 4731-17. Rules that establish the minimum requirements for universal precautions are essential for the protection of the patients when invasive procedures are being performed.

The Medical Board first thought that the rules in Chapter 4731-19 would need to be amended. But the research supports rescinding the rules.

**11. Did the Agency specifically consider a performance-based regulation? Please explain.**

***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The rules in Chapter 4731-17 are performance based. The rules set out the standards but do not require specific protocols or the use of specific types of disinfection or sterilizing techniques or devices.

The rules in Chapter 4371-19 are proposed to be rescinded.

**12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The Medical Board is the only agency that regulates health care providers to whom the rules in Chapter 4731-17 apply. The rules are consistent with the guidelines issued by the CDC and OSHA.

In rescinding the rules in Chapter 4731-19, the Medical Board is removing a level of bureaucracy that is no longer required in favor of more localized monitoring by hospitals.

**13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

Notice of the amended rules in Chapter 4731-17 and the rescission of the rules in Chapter 4731-19 will be sent to licensees and interested parties and posted on the Medical Board's website. Information about the amended rules will be included in the newsletter sent to all licensees.

**Adverse Impact to Business**

**14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community;**

For the universal precaution rules in Chapter 4731-17, the impacted business community is composed of all physicians, physician assistants, cosmetic therapists, acupuncturists, oriental medicine practitioners, anesthesiologist assistants, and radiologist assistants who perform invasive procedures. The health care entity through which the health care provider performs the invasive procedure will bear the monetary cost.

There is no adverse impact from rescinding the rules in Chapter 4371-19. Instead, the licensees currently monitored by the Medical Board will no longer incur the costs of having their own health care provider send periodic reports to the Medical Board.

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

The adverse impact is the cost of the equipment and materials and salaries of workers who perform sterilization and disinfection procedures required to comply with the rules. A licensee who fails to comply with the rules may incur administrative discipline from the Medical Board, with the possible penalties ranging from reprimand to permanent revocation of the license, as well as fines up to twenty thousand dollars.

**c. Quantify the expected adverse impact from the regulation.**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

The cost of compliance with the rules in Chapter 4731-17 will depend upon the means selected to comply. For example, the cost to comply with 4371-17-03 depends upon the costs of gloves, soap, and water. There are many variables in the pricing of equipment used for disinfection and sterilization and pricing information is not available to the public. The cost of workers to perform the sterilization and disinfection depends upon the salary, or the contract amount if the activity is contracted out.

**15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

That universal precautions should be employed to help prevent the transmission of infections in the health care setting is a fundamental principle in medicine. OSHA information states, “Universal precautions is an approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, HBV and other bloodborne pathogens...”

<https://www.osha.gov/SLTC/etools/hospital/hazards/univprec/univ.html>. Universal precautions protect the patient and the health care provider from infections that are transferred via instruments used in invasive procedures. When universal precautions are not followed, contaminated medical instruments, tools, and the hands of health care providers can serve as the vehicle for the spread of disease and infections.

**Regulatory Flexibility**

**16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

The rules in Chapter 4731-17 do not provide any exemptions or alternative means of compliance for small businesses. The use of universal precautions is essential in all health care settings, regardless the size of the business.

The rules in Chapter 4731-19 are proposed to be rescinded.

**17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

There are no reporting requirements for the rules in Chapter 4731-17.

**18. What resources are available to assist small businesses with compliance of the regulation?**

The Medical Board staff is available to answer questions concerning the rules in Chapter 4731-17.

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.**

Licenses 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.~~patient; and
  - (2) Impervious backed paper, aluminium 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 patient.
- (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.

4731-19-01

**Definitions.**

~~As used in this chapter of the Administrative Code:~~

~~(A) "The board" means the state medical board of Ohio.~~

~~(B) "ODH" means the Ohio department of health.~~

~~(C) "HIV" means the human immunodeficiency virus.~~

~~(D) "HBV" means the hepatitis B virus with hepatitis E-antigen positive status.~~

~~(E) "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.~~

~~(F) "Invasive procedure" means any of the following:~~

~~(1) Any 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 premolar 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; or~~

~~(4) The performance of fluoroscopic procedures pursuant to section 4774.08 of the Revised Code.~~

~~(G) "Exposure-prone invasive procedures" means an invasive procedure in which there is a significant risk of contact between the blood or body fluids of the licensee and the blood or body fluids of the patient.~~

~~(1) Some characteristics of exposure-prone invasive procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the licensee's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site.~~

~~(2) An invasive procedure is exposure-prone if it presents a recognized risk of percutaneous injury to the licensee, and, in the event such an injury occurs, the licensee's blood is likely to contact the patient's body cavity, subcutaneous tissues or mucous membranes.~~

4731-19-02

**Licensee's duty to report infection with HIV or HBV.**

- ~~(A) A licensee who believes or has reason to believe that he or she is infected with HIV or HBV and who performs invasive procedures shall report that fact to the ODH or to an institutional review panel approved by ODH within forty eight hours or shall voluntarily refrain from performing invasive procedures until such time as a report has been made in compliance with this rule.~~
- ~~(B) A licensee who believes or has reason to believe that he or she is infected with HIV or HBV and who performs invasive procedures may report that fact to the board, consistent with paragraph (A) of this rule, in lieu of reporting to the ODH or to an institutional review panel approved by ODH. However, the board will require the infected licensee to submit to review and monitoring by the ODH or to an institutional review panel approved by ODH as provided in paragraph (B) of rule 4731-19-06 of the Administrative Code.~~
- ~~(C) A licensee who believes or has reason to believe that another licensee who performs invasive procedures is infected with HIV or HBV shall advise the infected licensee of the infected licensee's duty to report under either paragraph (A) or (B) of this rule within forty eight hours of learning of the licensee's HIV or HBV infected status.~~
- ~~(D) A licensee who believes or has reason to believe that another licensee is infected with HIV but who is prohibited by section 3701.243 of the Revised Code or any other prevailing state or federal law from divulging the basis of the reporting licensee's belief shall nonetheless report to the board as required by division (B) of section 4731.224 of the Revised Code and rule 4731-15-01 of the Administrative Code if the reporting licensee believes the infected licensee is otherwise practicing below minimum standard of care or is unable to practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness or has failed to comply with either paragraph (A) or (B) of this rule. The reporting licensee need not include in his or her report test results or other information which section 3701.243 of the Revised Code or any other prevailing state or federal law prohibits the reporting licensee from divulging.~~
- ~~(E) For purposes of section 4731.224 of the Revised Code and this rule, "believes" or "reason to believe" does not require absolute certainty or complete unquestioning acceptance; but only an opinion that a licensee is infected with HIV or HBV based upon firsthand knowledge or reliable information.~~

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4731-19-03

**Confidentiality; reporting by board.**

~~Except as provided in paragraph (B) of rules 4731-19-02 and 4731-19-06 of the Administrative Code, the board shall hold in strict confidence all information in its possession relating to the HIV status and HBV status of a licensee who is or may be infected with HIV or HBV, provided that if the board initiates formal disciplinary proceedings pursuant to section 4730.25, 4731.22, 4760.13 or 4762.13 of the Revised Code it may disclose such information to the extent the board deems necessary to prove its allegations.~~

4731-19-04

**Voluntary compliance.**

~~In any disciplinary proceeding brought by the board against a licensee alleging violations related to the practitioner's professional activities or mental or physical status while HIV or HBV infected, the licensee may offer evidence that he or she has voluntarily complied with an evaluation, monitoring and any practice restrictions imposed by an ODH review panel, an institutional review panel approved by ODH, or the board. That evidence shall be considered by the board in deciding whether the practitioner has violated a statute upon which discipline may be based and, if it finds a violation, in deciding what, if any, discipline is appropriate.~~

4731-19-05

**Duty to refrain from certain procedures.**

- ~~(A) A licensee who knows he or she is infected with HIV or HBV shall not perform or participate in an exposure-prone invasive procedure, as that term is defined in paragraph (G) of rule 4731-19-01 of the Administrative Code, until the infected licensee has obtained counsel from the ODH review panel or from an institutional review panel approved by ODH and then, only under the circumstances that the counseling panel decides are appropriate. Such circumstances shall include notifying prospective patients of the licensee's seropositivity before they undergo any exposure-prone invasive procedures identified as such by the infected licensee's ODH review panel or institutional review panel approved by the ODH, and adherence to all guidelines published by the centers for disease control, and the United States department of health and human services.~~
- ~~(B) A licensee who has reason to suspect that he or she may be infected with HIV or HBV shall obtain appropriate testing to reveal the licensee's HIV status and HBV status before the licensee performs or participates in an exposure-prone invasive procedure.~~
- ~~(C) A licensee who knows or should suspect that he or she is infected with HIV or HBV shall practice recommended surgical technique and shall adhere to universal precautions, as delineated in Chapter 4731-17 of the Administrative Code, when performing invasive procedures other than exposure-prone invasive procedures.~~
- ~~(D) A violation of any provision of this rule shall also constitute "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances whether or not actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25, division (B)(6) of section 4731.22, division (B)(4) of section 4760.13, division (A)(4) of section 4762.13, and division (B)(4) of section 4774.13 of the Revised Code.~~

4731-19-06

**Board procedures.**

The following procedures shall be followed if the board receives information suggesting that a licensee is infected with HIV or HBV:

- (A) ~~The board shall record a complaint and investigate to determine whether the licensee is infected with HIV or HBV; whether the licensee is likely to perform or participate in an invasive procedure; and whether there is evidence that the licensee has violated any provision of section 4730.25, 4731.22, 4760.13, 4762.13, or 4774.13 of the Revised Code.~~
- (B) ~~If investigation confirms that the licensee is one who performs invasive procedures and is infected with HIV or HBV but produces insufficient evidence which would support formal discipline based on violations of section 4730.25, 4731.22, 4760.13, 4762.13, or 4774.13 of the Revised Code or any rule of the board, the board will refer the licensee to ODH for evaluation and monitoring as provided in paragraph (B) of rule 4731-19-02 of the Administrative Code.~~
- (1) ~~If the licensee who performs invasive procedures fails to verify to the board his or her compliance with the requirements of the monitoring program established by the ODH review panel or institutional review panel approved by ODH, the board will enter the licensee into its confidential monitoring program as provided in rule 4731-19-07 of the Administrative Code.~~
- (2) ~~The board will refrain from initiating disciplinary proceedings so long as the licensee complies with the requirements of the confidential monitoring program and so long as the board does not have evidence which support charges of violations of section 4730.25, 4731.22, 4760.13, 4762.13, or 4774.13 of the Revised Code.~~
- (C) ~~If investigation produces evidence which would support formal discipline and additionally confirms that the licensee is infected with HIV or HBV, the board shall initiate formal disciplinary proceedings based on the alleged violations of law, and may also enter the licensee into the confidential monitoring program. The board will treat all information relating to the licensee's infection with HIV or HBV as confidential, and will divulge the information only to the extent necessary to prove its allegations in the disciplinary proceedings.~~
- (D) ~~A licensee who has been entered into the confidential monitoring program who fails to comply with the requirements of the program will be subject to discipline for violations of division (B)(20) of section 4731.22, division (B)(3) of section 4730.25, division (B)(3) of section 4760.13, division (B)(3) of section 4762.13, or division (B)(3) of section 4774.13 of the Revised Code, as applicable to the licensee.~~

4731-19-07

**Confidential monitoring program.**

~~(A) A licensee who the board's secretary and supervising member have confirmed is infected with HIV or HBV and who performs invasive procedures and who is not participating in the evaluation and monitoring program run by ODH or by an institutional review panel approved by ODH shall participate in the confidential monitoring program. Upon identification of the infected licensee, the secretary will notify the board's compliance officer, who will be responsible for verifying the licensee's identity, license number, license status and specialties.~~

~~(B) The compliance officer will contact the licensee being monitored to:~~

~~(1) Provide copies of the board's rules in Chapter 4731-17 and 4731-19 of the Administrative Code and request the licensee's written agreement to comply with all requirements of those chapters;~~

~~(2) Request the licensee to identify in writing his or her treating physician, and to notify the board of any change of treating physician;~~

~~(3) Request the licensee to identify in writing the licensee's evaluation and monitoring panel, which shall be an institutional based review panel approved by ODH or an ODH review panel;~~

~~(4) Notify the licensee of the board's monitoring schedule, and request the licensee to contact the licensee's treating physician and evaluation and monitoring panel to authorize release of information to the board as requested; and~~

~~(5) Explain that confidentiality will be maintained so long as the licensee participates in the program and is not subject to board disciplinary action of a nature requiring disclosure of program information.~~

~~(C) Three months after the board's initial notification, and every June and December thereafter, the compliance officer shall monitor compliance by contacting the licensee, the licensee's designated treating physician and the licensee's evaluation and monitoring panel. The method of monitoring will be determined by the board's secretary on a case-by-case basis in order to assure confidentiality.~~

~~(1) The compliance officer shall request a written report from the licensee verifying the licensee's compliance with the requirements of Chapters 4731-17 and 4731-19 of the Administrative Code, updating the licensee's professional activities, and identifying any malpractice cases filed or decided against the licensee, any privilege actions or peer review organization actions taken against the licensee, and any other problems the licensee has experienced. The licensee shall timely submit the report, providing the information requested.~~

~~(2) The compliance officer shall request a written report from the licensee's designated treating physician concerning the licensee's health status, mental~~

~~health status and the course of treatment being undertaken, including a list of the medications the licensee is on. The treating physician shall timely submit the report, providing all information requested.~~

~~(3) The compliance officer shall request a written report from the licensee's designated evaluation and monitoring panel concerning the licensee's professional performance, including the licensee's current ability to practice according to minimum standards of care and the licensee's compliance with all practice restrictions and monitoring requirements imposed by the panel and by the board.~~

~~(D) The board's secretary and supervising member will review all reports received to determine if any action is appropriate. If the secretary and supervising member determine that current monitoring and restrictions are inadequate to assure public protection, they may implement additional monitoring requirements or practice restrictions.~~

~~(E) The board's compliance officer shall maintain all records related to the confidential monitoring program in a locked, secure location. In order to ensure confidentiality of reporting, all reports, correspondence and memoranda shall use identification codes rather than names. The identification codes shall be provided by the board. Access to the key which identifies licensees to whom identification codes are assigned will be strictly limited to the board's secretary, supervising member, compliance officer, and other board staff as directed by the secretary and supervising member for action on a particular case.~~