



You are invited to submit comments concerning the following rules, with comments due by **February 11, 2016**:

RULES IN CHAPTER 4731-18, Ohio Administrative Code: Surgery Standards

The rules in Chapter 4731-18 set the standards for surgery and regulate the use of light based medical devices.

For most of the rules the Medical Board has not proposed changes in content. This does not necessarily mean that the Medical Board does not anticipate amending the rules. In lieu of sending proposed amendments to the public, the Medical Board is asking for public input on the current rules and suggested changes to them in order to gauge areas of concern. The comments will be reviewed for possible inclusion into proposed amendments to the rules

The Medical Board is particularly interested in comments concerning updates in technology and any safety concerns about the use of specific devices.

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| 4731-18-01 | Standards for surgery: <i>Paragraph (A)(4) is amended to use gender neutral language.</i> |
| 4731-18-02 | Use of light based medical devices: <i>No changes proposed.</i> |
| 4731-18-03 | Delegation of the use of light based medical devices: <i>No changes proposed.</i> |
| 4731-18-04 | Delegation of the use of light based medical devices; Exceptions: <i>No changes proposed.</i> |

Please send comments to Sallie.Debolt@med.ohio.gov by February 11, 2016.

4731-18-01

Standards for surgery.

(A) The surgeon of record in an operative case shall personally:

- (1) Evaluate the patient sufficiently to formulate an appropriate preoperative diagnosis; and
- (2) Select the operation to be performed in consultation with the patient or with a person authorized to act on his behalf; and
- (3) Determine, based on his own evaluation, and, as necessary, on consultation with other physicians involved in the patient's care, that the patient is a fit candidate for the operation to be performed; and
- (4) Assure that the patient or a person authorized to act on ~~his~~ [the patient's](#) behalf gives informed consent before the surgery begins; and
- (5) Comply with division (B)(6) of section 4731.22 of the Revised Code; and
- (6) Perform or personally supervise the surgery, except those portions of the surgery, if any, which are performed or supervised by another qualified surgeon with the informed consent of the patient.

(B) Management of postoperative medical care is the responsibility of the surgeon of record. The surgeon of record shall fulfill this responsibility by:

- (1) Personally performing the postoperative medical care; or
- (2) Delegating postoperative medical care to another physician or physicians who are qualified by training and experience to provide the level of care required, provided that the surgeon of record shall remain primarily responsible for the patient's overall care unless the patient and the other physician have agreed in advance to shift that responsibility to the other physician; or
- (3) Delegating defined aspects of the postoperative medical care to appropriately trained and supervised allied health care personnel in compliance with applicable standards, provided that the surgeon of record shall retain personal responsibility for the quality of the care rendered by personnel who are under his supervision and control. The surgeon of record shall obtain the patient's fully informed consent, or the consent of a person authorized to act on the patient's behalf, in advance of surgery, before delegating aspects of patient care to allied health care personnel under this paragraph. The surgeon of record need not obtain the patient's informed consent for aspects of care to

which the patient has already consented, such as consent to treatment and care by hospital personnel under an informed consent form signed upon the patient's admission to the hospital; or

- (4) Delegating defined aspects of the postoperative medical care to licensees of other health regulatory boards who are licensed to independently provide the scope of practice and the level of care required, provided that the surgeon of record shall remain primarily responsible for the patient's overall care and must examine the patient during the postoperative period.
- (C) This rule shall not be read to transfer any responsibility which currently rests with any other physician, allied health care provider, or institution to the surgeon of record.
- (D) This rule shall not be read to prohibit or interfere with the appropriate training of medical students and physicians in post-graduate training programs, or other personnel.
- (E) The provisions of this rule requiring consultation with or obtaining the informed consent of the patient or a person legally authorized to act on his behalf do not apply to the extent they would prevent the performance of surgery or other procedures under emergency circumstances.

4731-18-02

Use of light based medical devices.

- (A) For purposes of this rule, light based medical device shall mean any device that can be made to produce or amplify electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nm but less than or equal to 1.0×10^6 nm and that is manufactured, designed, intended or promoted for in vivo irradiation of any part of the human body for the purpose of affecting the structure or function of the body.
- (B) The application of light based medical devices to the human body is the practice of medicine and surgery, osteopathic medicine and surgery and podiatric medicine and surgery.
- (C) Except as provided in rule 4731-18-03 and rule 4731-18-04 of the Administrative Code, no physician licensed pursuant to Chapter 4731. of the Revised Code shall delegate the application of light based medical devices to the human body to any person not authorized to practice medicine and surgery, osteopathic medicine and surgery or podiatric medicine and surgery pursuant to Chapter 4731. of the Revised Code.
- (D) A violation of paragraph (C) of this rule shall 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)(6) of section 4731.22 of the Revised Code and "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in division (B)(20) of section 4731.22 of the Revised Code, to wit: section 4731.41 of the Revised Code.

4731-18-03

Delegation of the use of light based medical devices.

- (A) A physician licensed pursuant to Chapter 4731. of the Revised Code may delegate the application of light based medical devices only for the purpose of hair removal and only if all the following conditions are met:
- (1) The light based medical device has been specifically approved by the United States food and drug administration for the removal of hair from the human body; and
 - (2) The use of the light based medical device for the purpose of hair removal is within the physician's normal course of practice and expertise; and
 - (3) The physician has seen and personally evaluated the patient to determine whether the proposed application of a light based medical device is appropriate; and,
 - (4) The physician has seen and personally evaluated the patient following the initial application of a light based medical device, but prior to any continuation of treatment in order to determine that the patient responded well to that initial application; and,
 - (5) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant registered pursuant to Chapter 4730. of the Revised Code and the physician has a board approved supplemental utilization plan allowing such delegation; or,
 - (b) A cosmetic therapist licensed pursuant to Chapter 4731. of the Revised Code; or,
 - (c) A registered nurse or licensed practical nurse licensed pursuant to Chapter 4723. of the Revised Code; and,
 - (6) The person to whom the delegation is made has received adequate education and training to provide the level of skill and care required; and,
 - (7) The physician provides on-site supervision at all times the person to whom the delegation is made is applying the light based medical device; and,
 - (8) The physician supervises no more than two persons pursuant to this rule at the same time.

(B) Notwithstanding paragraph (A)(7) of this rule, the physician may provide off-site supervision when the the light based medical device is applied to an established patient if the person to whom the delegation is made pursuant to paragraph (A) of this rule is a cosmetic therapist licensed pursuant to Chapter 4731. of the Revised Code who meets all of the following criteria:

- (1) The cosmetic therapist has successfully completed a course in the use of light based medical devices for the purpose of hair removal that has been approved by the board; and
- (2) The course consisted of at least fifty hours of training, at least thirty hours of which was clinical experience; and
- (3) The cosmetic therapist has worked under the on-site supervision of the physician making the delegation a sufficient period of time that the physician is satisfied that the cosmetic therapist is capable of competently performing the service with off-site supervision.

The cosmetic therapist shall maintain documentation of the successful completion of the required training.

(C) The cosmetic therapist, physician assistant, registered nurse or licensed practical nurse shall immediately report to the supervising physician any clinically significant side effect following the application of the light based medical device or any failure of the treatment to progress as was expected at the time the delegation was made. The physician shall see and personally evaluate the patient who has experienced the clinically significant side effect or whose treatment is not progressing as expected as soon as practicable.

(D) For purposes of this rule, on-site supervision requires the physical presence of the supervising physician in the same location (i.e., the physician's office suite) as the cosmetic therapist, physician assistant, registered nurse or licensed practical nurse, but does not require his or her presence in the same room.

(E) For purposes of this rule, off-site supervision means that the supervising physician shall be continuously available for direct communication with the cosmetic therapist and must be in a location that under normal conditions is not more than sixty minutes travel time from the cosmetic therapist's location.

(F) A violation of paragraph (A) (B) or (C) of this rule by a physician shall 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)(6) of section 4731.22 of the Revised Code. A violation of division (A)(5) of this rule shall constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in division (B)(20) of section 4731.22 of the Revised Code, to wit: section 4731.41 of the Revised Code.

- (G) A violation of paragraph (C) of this rule by a cosmetic therapist shall 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)(6) of section 4731.22 of the Revised Code. A violation of paragraph (C) of this rule by a physician assistant shall constitute a "departure from, or failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances, regardless of whether actual injury to patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code.

4731-18-04

**Delegation of the use of light based medical devices;
Exceptions.**

- (A) A physician authorized pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may delegate to any appropriate person the application of light based medical devices approved by the United States food and drug administration for phototherapy in treatment of hyperbilirubinemia in neonates.
- (B) A physician authorized pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may delegate to any appropriate person the application of a light based medical device that is a fluorescent lamp phototherapy device for treatment of psoriasis and similar skin diseases. A fluorescent lamp phototherapy device is a device that emits ultraviolet light through the use of one or more fluorescent bulbs and is approved by the United States food and drug administration for phototherapy in the treatment of psoriasis or similar skin diseases.