

The State Medical Board of Ohio reviewed Rules 4731-18-01, 4731-18-02, 4731-18-03, and 4731-18-04 pursuant to the requirement that rules be reviewed every five years. The Medical Board's proposed revisions to the Chapter 4731-18 rules and the transferring of current rule 4731-18-01 into the surgery chapter as new rule 4731-25-08 are being sent to you for your comment. You may submit comments supporting or disagreeing with the language of the rules as proposed. All comments will be considered, and may result in changes to the proposed language.

The invitation to comment is the first step in the rule adoption process. The proposed rules must next be reviewed by the Common Sense Initiative Office ("CSI") which will include another public comment period. Upon CSI's recommendation, the proposed rules will be filed with the Joint Committee on Agency Rule Review ("JCARR"), upon which there will be a public hearing for the receipt of interested party comments.

Proposed rules 4731-18-01, 4731-18-02, 4731-18-03, 4731-18-04, and 4731-25-08 can be found on the Medical Board's website at the following link:

<http://med.ohio.gov/LawsRules/NewlyAdoptedandProposedRules.aspx>. Scroll down to "Proposed Rules Under Initial Review."

A summary of the proposed changes to the rules is detailed below.

4731-18-01: Definitions

- Consolidates all definitions in the chapter and adds new definitions including: "phototherapy" (B), "phototherapy devices" (C), "photodynamic therapy" (D), "ablative dermatologic procedure" (E), "non-ablative dermatologic procedure", "physician" (G), and "delegation" (H).

4731-18-02 Use of light based medical devices

- Lays out framework for physician delegation of the application of light based medical devices based on the distinction between ablative and non-ablative procedures.
- Paragraph (B) states that a physician shall not delegate application of light based medical devices for ablative procedures.
- Paragraphs (C), (D), and (E) provide for the delegation of the application of light based medical devices for specified non-ablative dermatologic procedures and the treatment of hyperbilirubinemia in neonates according to the requirements in subsequent rules.

4731-18-03: Delegation of the use of light based medical devices for specified non-ablative procedures

- Paragraph (A) adds the ability of physicians to delegate vascular laser non-ablative procedures to a physician assistant, R.N., or L.P.N. if specified conditions are met including: physician evaluates patient before and after the first application of the vascular laser; delegate has completed eight (8) hours of education; observed fifteen (15)

procedures; performed twenty (20) procedures under direct physical oversight of physician; and physician provides on-site supervision.

- Paragraph (B) retains current rule on laser hair removal delegation by a physician, but adds robust education and training requirements including eight (8) hours of education; observation of fifteen (15) procedures; and performance of twenty (20) procedures under direct physical oversight of physician.

4731-18-04: Delegation of phototherapy and photodynamic therapy

- Paragraph (A) adds specificity to physician delegation of the application of phototherapy in the treatment of hyperbilirubinemia in neonates to include a physician assistant, R.N., and L.P.N. This paragraph also requires training and on-site physician supervision.
- Paragraph (B) also adds specificity to physician delegation of phototherapy for psoriasis and other skin diseases to include a physician assistant, R.N., L.P.N., and medical assistant who has successfully completed training. This paragraph requires on-site physician supervision as well.
- Adds physician delegation of photodynamic therapy for dermatologic purposes to a physician assistant, R.N. and L.P.N. in paragraph (C) with the requirements that the delegate complete training and that the physician provides on-site supervision.
- Requires reporting of adverse events and failure of treatment by all delegates, and requires physician to personally evaluate patient when this occurs in paragraph (D).
- Lays out the disciplinary framework for violations of (A), (B), (C), and (D).

4731-25-08 Standards for Surgery

- Moves current rule 4731-18-01 into the surgery chapter (4731-25) and makes minor grammatical changes.

Comments must be received by the end of the business day on February 2, 2018.

Send comments to: Nathan.Smith@med.ohio.gov

Chapter 4731-18 Surgery Standards Light Based Procedures

4731-18-01 Standards for Surgery Definitions

~~(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 patient's behalf; and~~

~~(3) Determine, based on his surgeon's 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 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 patient's behalf do not apply to the extent they would prevent the performance of surgery or other procedures under emergency circumstances.~~

As used in this chapter of the Administrative Code:

- (A) "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 [ten to the sixth power] 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) "Phototherapy" means the application of ultraviolet light for the treatment of skin diseases and disorders such as hyperbilirubinemia.
- (C) "Phototherapy device" means any device **cleared or** approved by the United States food and drug administration **for the indicated use** that can be made to produce irradiation with broadband ultraviolet B (290-320nm), narrowband ultraviolet B (311-313 nm), excimer light based (308nm), ultraviolet A1 (340-400nm), or UVA (320-400nm) plus oral psoralen called PUVA.
- (D) "Photodynamic therapy" means light therapy involving the activation of a photosensitizer by visible light in the presence of oxygen, resulting in the creation of reactive oxygen species, which selectively destroy the target tissue.
- (E) "Ablative dermatologic procedure" means a dermatologic procedure that is expected to excise, burn, or vaporize the skin below the dermo-epidermal junction.
- (F) "Non-ablative dermatologic procedure" means a dermatologic procedure that is not expected or intended to excise, burn, or vaporize the epidermal surface of the skin.
- (G) "Physician means a person authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery under Chapter 4731. and acting within the scope of their practice.

- (H) “Delegation” means the assignment of the performance of a service to a person who is not a physician.
- (I) “On-site supervision” means the physical presence of the supervising physician is required in the same location (i.e., the physician's office suite) as the delegate of the light based medical device but does not require the physician’s presence in the same room.
- (J) “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.

4731-18-02 Use of light based medical devices

- (A) The application of light based medical devices to the human body is the practice of medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.
- (B) A physician shall not delegate the application of light based medical devices for ablative procedures.
- (C) A physician may delegate the application of a vascular laser for non-ablative dermatologic procedures according to the requirements in paragraph (A) of rule 4731-18-03 of the Administrative Code.
- (D) A physician may delegate the application of light based medical devices for the purpose of hair removal according to the respective requirements in paragraphs (B) and (C) of rule 4731-18-03 of the Administrative Code.
- (E) A physician may delegate the application of phototherapy and photodynamic therapy **only for the treatment of hyperbilirubinemia and dermatologic purposes respectively** according to the requirements of rule 4731-18-04 of the Administrative Code.
- (F) A violation of paragraph ~~(C)~~ (B) 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 for specified non-ablative procedures

- (A) A physician may delegate the application of a vascular laser for non-ablative dermatologic procedures only if all the following conditions are met:

- (1) The vascular laser has been specifically **cleared or** approved by the United States food and drug administration for the specific intended non-ablative dermatologic procedure;
- (2) The use of the vascular laser for the specific non-ablative dermatologic use is within the physician's normal course of practice and expertise;
- (3) The physician has seen and personally evaluated the patient to determine whether the proposed application of the vascular laser is appropriate;
- (4) The physician has seen and personally evaluated the patient following the initial application of the vascular laser, but prior to any continuation of treatment in order to determine that the patient responded well to the initial application of the vascular laser;
- (5) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement authorizing the service; or,
 - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;
- (6) The person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:
 - (a) Eight (8) hours of basic training on the following topics: light based procedure physics, tissue interaction in light based procedures, light based procedure safety including use of proper safety equipment, clinical application of light based procedures, pre and post-operative care of light based procedure patients, and reporting of adverse events;
 - (b) Observation of fifteen (15) procedures for each specific vascular laser non-ablative procedure delegated;
 - (c) Performance of twenty (20) procedures under the direct physical oversight of the physician on each specific vascular laser non-ablative procedure delegated; and
 - (d) Satisfactory completion of training shall be documented by the physician delegating and the delegate;
- (7) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,
- (8) The physician supervises no more than two persons pursuant to this rule at the same time.

- (B) A physician 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 **cleared or** 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~~ licensed ~~pursuant to~~ under Chapter 4730. of the Revised Code ~~and with whom the physician has a board approved supplemental utilization plan allowing such delegation~~ an effective supervision agreement authorizing the service; ~~or~~,
 - (b) A cosmetic therapist licensed ~~pursuant to~~ under Chapter 4731. of the Revised Code; or,
 - (c) A registered nurse or licensed practical nurse licensed ~~pursuant to~~ under 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 including:
 - (a) Eight (8) hours of basic training on the following topics: light based procedure physics, tissue interaction in light based procedures, light based procedure safety including use of proper safety equipment, clinical application of light based procedures, pre and post-operative care of light based procedure patients, and reporting of adverse events;
 - (b) Observation of fifteen (15) procedures for each specific light based procedure for hair removal delegated;
 - (c) Performance of twenty (20) procedures under the direct physical oversight of the physician on each specific light based procedure for hair removal delegated; and
 - (d) Satisfactory completion of training shall be documented by the physician delegating and the delegate;
 - (7) The physician provides on-site supervision at all times that 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.

(C) Notwithstanding paragraph (B)(7) of this rule, the physician may provide off-site supervision when the light based medical device is applied for the purpose of hair removal to an established patient if the person to whom the delegation is made pursuant to paragraph ~~(A)~~ (B) of this rule is a cosmetic therapist licensed ~~pursuant to~~ under 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.

(D) 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.

(E) A violation of paragraph (A), (B), ~~or (C)~~, or (D) 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.

(F) A violation of division (A)(5) or (B)(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 (D) of this rule by a cosmetic therapist shall constitute "A 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.

(H) A violation of paragraph (D) 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 phototherapy and photodynamic therapy

(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 **cleared or** approved by the United States food and drug administration for phototherapy in treatment of hyperbilirubinemia in neonates only if all the following conditions are met:

- (1) The use of the light based medical device for this treatment is within the physician's normal course of practice and expertise.
- (2) The physician has seen and personally evaluated the patient to determine whether the proposed application of phototherapy is appropriate;
- (3) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement authorizing the service; or,
 - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;
- (4) The person to whom the delegation is made completes basic training on hyperbilirubinemia in neonates and clinical training in the administration of phototherapy to neonates;
- (5) The completion of this training is documented by the person to whom the delegation is made; and
- (6) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the phototherapy.

(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 **that is cleared or approved by the United States food and drug administration** for treatment of psoriasis and similar skin diseases ~~only under~~ if all

the following conditions are met: 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.

- (1) The use of the light based medical device for this treatment is within the physician's normal course of practice and expertise.
 - (2) The physician has seen and personally evaluated the patient to determine whether the proposed application of phototherapy is appropriate;
 - (3) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement authorizing the service;
 - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code; or
 - (c) A **certified** medical assistant who has successfully completed and documented the completion of basic training on psoriasis and similar skin diseases and clinical training in the administration of the phototherapy device for the specific skin disease being treated; and
 - (4) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the phototherapy.
- (C) A physician may delegate the application of light based medical devices **cleared or approved** by the United States food and drug administration for photodynamic therapy for dermatologic purposes only if all the following conditions are met:
- (1) The use of the light based medical device for this treatment is within the physician's normal course of practice and expertise.
 - (2) The physician has seen and personally evaluated the patient to determine whether the proposed application of photodynamic therapy is appropriate;
 - (3) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement authorizing the service; or,
 - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;
 - (4) The person to whom the delegation is made completes basic training on photodynamic therapy and clinical training in the administration of photodynamic therapy for the specific disease or disorder being treated;
 - (5) The completion of this training is documented by the person to whom the delegation is made; and
 - (6) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the photodynamic therapy.
- (D) Any person to whom a lawful delegation of phototherapy or photodynamic therapy has been made shall immediately report to the supervising physician any clinically significant side effect following the application of the phototherapy or photodynamic

therapy 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.

- (E) A violation of paragraph (A), (B), (C), or (D) 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)(2), (B)(2), or (C)(2) 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.
- (F) A violation of paragraph (D) 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.

Chapter 4731-25 ~~Office Based~~ Surgery

4731-18-01 4731-25-08 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~~ the patient's behalf; and
 - (3) Determine, based on ~~his~~ the surgeon's 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~~ in one of the following ways:

(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~~ the patient's behalf do not apply to the extent they would prevent the performance of surgery or other procedures under emergency circumstances.