

4731-18-01

Definitions.

As used in this chapter of the Administrative Code:

- (A) “Light based medical device ” means 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 irradiation of any part of the human body for the purpose of affecting the structure or function of the body.
- (B) “Phototherapy” means the following:
- (1) For paragraph (A) of rule 4731-18-04 of the Administrative Code, phototherapy means the application of light for the treatment of hyperbilirubinemia in neonates.
 - (2) For paragraphs (B) and (C) of rule 4731-18-04 of the Administrative Code, phototherapy means the application of ultraviolet light for the treatment of psoriasis and similar skin diseases. This application can occur with 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.
- (C) “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.
- (D) “Ablative dermatologic procedure” means a dermatologic procedure that is expected to excise, burn, or vaporize the skin below the dermo-epidermal junction.
- (E) “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.
- (F) “Physician means a person authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery under Chapter 4731. of the Revised Code and acting within the scope of their practice.
- (G) “Delegation” means the assignment of the performance of a service to a person who is not a physician.

(H) "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.

~~(I) "Off-site supervision" means that the supervising physician shall be continuously available for direct communication with the cosmetic therapist.~~

~~(I)~~(I) "Direct physical oversight" means the physical presence of the supervising physician is required in the same room to directly observe the delegate of the light based medical device.

~~(K)~~(J) "Vascular laser" means light-based medical devices including lasers and intense pulsed light apparatuses whose primary cutaneous target structures are telangiectasia, venulectasia, and superficial cutaneous vascular structures. In general, these lasers have wavelengths that correspond to the hemoglobin absorption spectrum.

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 [of section 4731.33 of the Revised Code](#).~~in paragraphs (B) and (C) of rule 4731-18-03 of the Administrative Code.~~
- (E) A physician may delegate the application of phototherapy for the treatment of hyperbilirubinemia in neonates according to the requirements in paragraph (A) of rule 4731-18-04 of the Administrative Code.
- (F) A physician may delegate the application of phototherapy and photodynamic therapy only for dermatologic purposes according to the requirements of paragraphs (B) and (C) of rule 4731-18-04 of the Administrative Code.
- (G) A violation of paragraph (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 evaluated the patient to determine whether the proposed application of the specific vascular laser is appropriate;

(4) The physician has seen and evaluated the patient following the initial application of the specific vascular laser, but prior to any continuation of treatment in order to determine that the patient responded well to the initial application of the specific 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; or,

(b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;

(6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.

(7) For a registered nurse or licensed practical nurse, the physician must ensure that 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 hours of basic education that must include 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 procedures for each specific type of vascular laser non-ablative procedure delegated. The procedures observed must be performed by a physician for whom the use of this specific vascular laser procedure is within the physicians normal course of practice and expertise; and

(c) Performance of twenty procedures under the direct physical oversight of the physician on each specific type of vascular laser non-ablative procedure delegated. The physician overseeing the performance of these procedures must use this specific vascular laser procedure within the physicians normal course of practice and expertise;

(d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific vascular laser procedures delegated and the number of delegating physicians. The training requirements in paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physician;

(8) For delegation to a registered nurse or licensed practical nurse, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,

(9) For delegation to a registered nurse or licensed practical nurse, 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 for the purpose of hair removal in accordance with the requirements of section 4731.33 of the Revised Code.

(C) The 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) 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.

(E) 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.

(F) 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.

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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 evaluated the patient to determine whether the proposed application of the specific vascular laser is appropriate;
 - (4) The physician has seen and evaluated the patient following the initial application of the specific vascular laser, but prior to any continuation of treatment in order to determine that the patient responded well to the initial application of the specific 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; or,
 - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;
 - (6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.
 - (7) For a registered nurse or licensed practical nurse, the physician must ensure that 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 hours of basic education that must include 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 procedures for each specific type of vascular laser non-ablative procedure delegated. The procedures observed must be performed by a physician for whom the use of this specific vascular laser procedure is within the physician's normal course of practice and expertise; and
 - (c) Performance of twenty procedures under the direct physical oversight of the physician on each specific type of vascular laser non-ablative procedure delegated. The physician overseeing the performance of these procedures must use this specific vascular laser procedure within the physician's normal course of practice and expertise;
 - (d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific vascular laser procedures delegated and the number of delegating physicians. The training requirements in paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physician;
- (8) For delegation to a registered nurse or licensed practical nurse, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,
- (9) For delegation to a registered nurse or licensed practical nurse, 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 for the purpose of hair removal 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;
 - (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;
 - (3) The physician has seen and evaluated the patient to determine whether the proposed application of the specific light based medical device is appropriate;

- (4) The physician has seen and evaluated the patient following the initial application of the specific light based medical device, but prior to any continuation of treatment in order to determine that the patient responded well to that initial application of the specific light based medical device;
- (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;
 - (b) A cosmetic therapist who was licensed under Chapter 4731. of the Revised Code on April 11, 2021 or who has completed a cosmetic therapy course of instruction for a minimum of seven hundred fifty clock hours and received a passing score on the “Certified Laser Hair Removal Professional ® Examination” administered by “The Society for Clinical and Medical Hair Removal”; or,
 - (c) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code.
- (6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.
- (7) For cosmetic therapists, registered nurses and licensed practical nurses, the physician shall ensure 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 hours of basic education that must include 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 procedures for each specific type of light based medical device procedure for hair removal delegated. The procedures observed must be performed by a physician for whom the use of this specific light based medical device procedure for hair removal is within the physician’s normal course of practice and expertise; and

- (c) Performance of twenty procedures under the direct physical oversight of the physician on each specific type of light based medical device procedure for hair removal delegated. The physician overseeing the performance of these procedures must use this specific light based medical device procedure for hair removal within the physician's normal course of practice and expertise;
 - (d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific light based medical device procedures for hair removal delegated and the number of delegating physicians. The training requirements of paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of light based medical device procedure for hair removal delegated regardless of the number of delegating physicians;
 - (e) Delegates who, prior to the effective date of this rule, have been applying a specific type of light based medical device procedure for hair removal for at least two years through a lawful delegation by a physician, shall be exempted from the education and training requirements of paragraphs (A)(7)(a), (A)(7)(b), and (A)(7)(c) of this rule for that type of procedure provided that they obtain a written certification from one of their current delegating physicians stating that the delegate has received sufficient education and training to competently apply that type of light based medical device procedure. This written certification must be completed no later than sixty days after the effective date of this rule, and a copy of the certification shall be retained by each delegating physician and each delegate.
 - (f) For cosmetic therapists, the education and training requirements of paragraph (A)(7)(a), (A)(7)(b), or (A)(7)(c) of this rule may be satisfied through the cosmetic therapy course of instruction in paragraph (B)(5)(b) of this rule if the program provides written verification to the physician that the cosmetic therapist completed the requirements of paragraph (A)(7)(a), (A)(7)(b), or (A)(7)(c) of this rule as part of the cosmetic therapy course of instruction.
- (8) For cosmetic therapists, registered nurses and licensed practical nurses, 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,

- (9) For cosmetic therapists, registered nurses and licensed practical nurses, the physician supervises no more than two persons pursuant to this rule at the same time.
- (C) Notwithstanding paragraph (B)(8) 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 (B) of this rule is a cosmetic therapist 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 delegating physician;
 - (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), (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 (C) or (D) of this rule by a cosmetic therapist shall constitute the unauthorized practice of medicine pursuant to section 4731.41 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.

The following rules are being circulated for comments from interested parties. The proposed changes are highlighted below.

4731-18-01	Definitions	Proposed to amend
4731-18-02	Use of Light Based Medical Devices	Proposed to amend
4731-18-03	Delegation of the Use of Light Based Medical Devices for Specified Non-Ablative Procedures	Proposed to rescind
4731-18-03	Delegation of the Use of Light Based Medical Devices for Specified Non-Ablative Procedures	Proposed new rule

Section 4731.33 of the Ohio Revised Code became effective September 30, 2021. The statutory section addresses the delegation of the use of light-based medical devices for hair removal. The proposed rule amendments remove any provisions where the rule language is in conflict or duplicative to the statutory language.

More than 50% of Rule 4731-18-03, so the changes are proposed through a rescission and a new rule.