



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Light Based Medical Device Rules

Rule Number(s): 4731-18-01, 4731-18-02, 4731-18-03

Date of Submission for CSI Review: 9/22/22

Public Comment Period End Date: 10/14/22

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ 2 rules (FYR?)

Rescinded/ 1 rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing

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regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☐ Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

- 2. Please briefly describe the draft regulation in plain language.**

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

Rule 4731-18-01: Establishes the definitions for this rule chapter.

Rule 4731-18-02: Establishes the use of light based medical devices is the practice of medicine and provides general information regarding the delegation of certain types of light based medical devices.

Rule 4731-18-03: Provides detail regarding the delegation of light based medical devices for specified non-ablative procedures.

- 3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Authorized by: 4730.07, 4731.05, 4731.33

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Amplifies: 4730.07, 4731.05, 4731.33, 4731.22, 4730.21, 4730.25, 4731.22, 4731.41

- 4. 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.

No.

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

Not applicable.

- 6. 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 public purpose of the proposed rules is to ensure public safety in the practice of medicine and surgery and the competent application of certain light based medical devices. The purpose of this particular filing is to align the rules with R.C. 4731.33 related to the delegation of light based medical devices for hair removal.

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

The success of these regulations will be measured by the safe application of certain light based medical devices with minimal adverse events; the rules being written in plain, understandable language, licensee compliance with the rules; and minimal questions from the licensees about the proposed rules.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

- 9. 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.

In November 2021, the Medical Board circulated the proposed rules to interested parties who have requested to receive rule updates, including the Ohio State Medical Association, the Academy of Medicine of Cleveland and Northern Ohio, the Ohio Hospital Association, the

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Ohio Physician Assistant Association, attorneys interested in matters before the Medical Board, and the Ohio Board of Nursing. The proposed rules were also posted on the Medical Board's website and were provided to the members of the Physician Assistant Policy Committee in February of 2022.

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

Four comments were received. Beth Adamson of the Ohio Association of Physician Assistants requested that the definition of "Ablative dermatologic procedure" in 4731-18-01(D) be updated because physician assistants are already performing procedures in office beneath the dermo-epidermal junction to the subcutaneous fact (such as excisions with intermediate and complex closures) without direct supervision. Ms. Adamson requested a change to Rule 4731-18-02(D) to state that a physician may delegate the application of light based medical devices for hair removal, resurfacing and dermatologic purposes because the current language is restrictive to specialty physician practices such as dermatology, ENT, facial plastic surgery and plastic and reconstructive surgery. Ms. Adamson requests the removal of paragraphs (A)(3), (4), and (5) of Rule 4731-18-03 because the requirement for the physician to evaluate the patient creates more work for the provider. Matthew Ernst and Jo Kelton of Removery, LLC recommended changes to the rules to allow delegation of laser tattoo removal to cosmetic therapists, physician assistants, registered nurses and licensed practical nurses. Amanda Nelson of the Cosmetic Therapy Association of Ohio recommended changes to Rules 4731-18-01 through 4731-18-03 which would allow cosmetic therapists to be delegated the use of light based medical devices for non-ablative vascular treatments.

The rules and comments were discussed at the February meeting of the Physician Assistant Policy Council. The members did not recommend any specific rule changes.

The Medical Board reviewed the comments at its meeting on April 13, 2022 and after a full discussion, determined not to make the proposed changes. The purpose of this rule review is to correct any discrepancies between the statute and the rules, which were finalized less than one year ago, after a very lengthy rule-making process. The rules were changed to allow physician assistants and nurses to be delegated the use of non-ablative vascular lasers because these are the safest for patients. Tattoo removal does not use a non-ablative vascular laser and is more complicated due to the different pigments used in tattoos. The Board wanted to keep the physician evaluation in paragraphs (A)(3) and (4) to ensure patient safety and that the use of the non-ablative vascular laser was appropriate for the patient's condition.

11. 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 Board used its medical expertise to develop the rules with a focus on ensuring patient safety.

12. 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?

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The Board carefully considered the comments but determined not to make substantive changes regarding the procedures around delegation of non-ablative vascular lasers nor to add tattoo removal as a laser procedure that could be delegated to physician assistants or nurses. The purpose of the amendments is to align the rules with the newly passed statute regarding laser hair removal.

- 13. 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 Medical Board did not consider a performance-based regulation because these proposed rules do not define the required outcome and instead seek to prevent adverse events.

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

The rule amendments are proposed to ensure that the rule does not duplicate or conflict with R.C. 4731.33.

- 15. 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.**

The rules will be posted on the Medical Board's website and notice of the rules will be circulated to the interested parties. Medical Board staff members will be available to answer questions regarding the rules. Board staff will be made aware of the rules' provisions so that the rules can be fairly, consistently, and predictably applied to the regulated community.

Adverse Impact to Business

- 16. 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; and**
- b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**
- 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 impacted business community includes physicians utilizing light-based medical devices in their practice, licensees to whom tasks are delegated, such as physician assistants, registered nurses and licensed practical nurses. The nature of the adverse impact is the

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eight hours of basic education that must be completed for the delegation of non-ablative procedures. In addition, the physicians will need to have the delegated licensees observe procedures and then provide direct physical oversight before the licensees can perform on their own. In addition, physicians who violate these rules are subject to disciplinary action and fines up to \$20,000 from the Medical Board.

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

The Medical Board determined that the regulatory intent justifies the adverse impact to the regulated business community because the Board endeavors to protect patients and ensure the competent application of the specified light based medical devices.

Regulatory Flexibility

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

No, the regulation does not provide exemptions or alternative means of compliance for small business. All practitioners utilizing light-based medical devices need to follow the same regulations for patient safety.

19. 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?

Due process requires the Medical Board to consistently apply its rules such that all licensees using light-based medical devices are equally treated.

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

Medical Board staff members are available by telephone and e-mail to answer questions.

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.~~

~~(J)~~(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.

*** DRAFT - NOT YET FILED ***

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 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.