



# Common Sense Initiative

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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 procedures

Rule Number(s): 4731-18-01 Definitions; 4731-18-02; Use of light based medical devices; 4731-18-03 Delegation of the use of light based medical devices for specified non-ablative procedures; 4731-18-04 Delegation of phototherapy and photodynamic therapy

Date of Submission for CSI Review: May 12, 2020

Public Comment Period End Date: May 27, 2020

Rule Type/Number of Rules:

New/ X rules

No Change/      rules (FYR?     )

Amended/   x   rules (FYR?yes     )

Rescinded/      rules (FYR?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 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.

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### **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.*

#### **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.
- Paragraph (B) states that a physician shall not delegate application of light based medical devices for ablative procedures.

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- Paragraphs (C), (D), and (E) provide for the delegation of the application of light based medical devices for specific types of non-ablative procedures 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 dermatologic 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 certified medical assistant who has successfully completed training. This paragraph requires on-site physician supervision as well.
- Adds photodynamic therapy delegation by a physician 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).

**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.**

The Medical Board is authorized to issue rules by R.C. 4730.07, R.C. 4731.05, and R.C. 4731.15. There is no specific statutory direction on the application of light based medical devices. However, the general rulemaking authority to regulate the practice of medicine and

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surgery gives the Medical Board authority to amend its rules in the evolving area of light based medicine in the practice of medicine and surgery.

- 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.*

The proposed regulations do not implement a federal requirement, nor are they being adopted or amended in connection with administering or enforcing a federal law or participating in a federal program.

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

The question is 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.

- 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. The rules are not being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931.

### **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.*

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On January 13, 2016, the Policy Committee of the Medical Board discussed the light based medical device rules in chapter 4731-18 and recommended that technical and medical expertise related to light based procedures be obtained.

Subsequently, Board staff communicated with an initial panel of five medical experts with experience in the application of light based medical devices. The expert panel included Dr. Mark Bechtel, Dr. Stephen Smith, Dr. Georgann Poulos, Dr. Eric Bernstein, and Dr. Ronald Siegle. These experts provided verbal or written comments on the existing Chapter 4731-18 rules and suggestions how to improve the rules. Doctors Smith and Poulos provided additional written comments to the initial circulation draft of the proposed rule as well.

Board staff also conducted extensive research into the regulation of light based medical device procedures by other states, adverse events involved in application of light based medical devices, and the light based medical device procedures themselves.

After obtaining the required technical and medical information through consultation with the expert panel and independent research, Board staff drafted the proposed rules. During the drafting process, Board Staff met with Dr. Bechtel, a member of the Board and the expert panel, to develop and review the draft of the proposed rules. Dr. Bechtel provided additional input for the draft on the issues of supervision and appropriate light based medical device education and training from his informal survey of doctors and residents associated with his practice with The Ohio State University Wexner Medical Center.

On January 10, 2018, the Board's Policy Committee publicly reviewed, discussed, and approved the proposed rules for initial circulation with a few amendments that did not change the overall substance of the rule. Board staff then circulated the proposed rules for comment to interested parties and all licensed doctors, physician assistants, and cosmetic therapists.

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

In response to the initial circulation, the Board received 46 written comments which can be categorized as follows:

1. Seven comments were generally supportive of the rules with no suggested changes.
2. Three comments raised questions and expressed concerns about the rules' lack of regulation of nurse practitioners and the interplay of the rules with Nursing Board regulation of nurse practitioners' application of light based medical devices.
3. Two comments were concerned with the definition of phototherapy for the treatment of hyperbilirubinemia in neonates. Two other comments expressed concern that the definition was too narrow for cosmetic procedures not regulated in these rules.
4. Five comments sought a definition or clarification of the term "vascular laser".

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5. Seven comments supported expanding the application of non-ablative light based medical devices beyond vascular lasers for dermatologic procedures and hair removal. Five of these seven comments supported expanding delegation to fractionated lasers often used for cosmetic procedures.
6. Four comments opposed expanding delegation of light based medical devices beyond hair removal to vascular lasers, or did not support physician's delegating the application of light based medical devices at all.
7. Two comments favored delegating light based medical device procedures to only physician assistants due to their more extensive education and training than that of other delegates. Two other comments were in favor of delegation to physician assistants and nurses, but not cosmetic therapists.
8. Three comments advocated delegating all light based medical device procedures, including ablative procedures, to physician assistants.
9. Three comments encouraged extending delegation of phototherapy and photodynamic therapy to cosmetic therapists.
10. Eight comments favored expanding off-site physician supervision beyond cosmetic therapists to all other delegates.
11. Nine comments did not agree with the requirements that the physician personally see patients before and after the initial application of a light based medical device, and sought to eliminate the initial evaluation, the follow-up evaluation, or both.
12. One comment requested clarification on whether the phrase "the physician has seen and personally evaluated the patient" allows for video or picture review by the physician instead of the physician being in the same room as the patient.
13. Five comments sought various changes to the rule's delegation of phototherapy in the treatment of hyperbilirubinemia in neonates.
14. One comment advocated extending the delegation of light based medical devices to tattoo removal, and allowing non-medical technicians to perform these procedures along with laser hair removal, skin rejuvenation, and acne treatment.
15. One comment argued that the rules' limited delegation of non-ablative dermatologic procedures was too restrictive and could possibly be in violation of antitrust laws.
16. Four comments had questions about or suggested changes to the new training requirements for delegates applying light based medical devices.
17. One comment inquired into whether delegates who had been lawfully practicing laser hair removal could be exempted from the rule's new education and training requirements. One other comment suggested a grandfather clause for practitioners who had been performing photodynamic therapy for years without regulation.

Board staff also met with two additional Board members, Dr. Andrew Schachat and Dr. Kim Rothermel, to discuss the effect of the proposed rules in their fields of ophthalmology and

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pediatrics respectively. Dr. Schachat expressed concern about the danger of delegating light based medical device procedures for purposes other than dermatologic ones due to the great potential for patient harm in areas like ophthalmology. Dr. Rothermel reported concerns in the hospital community about regulating phototherapy in the treatment of jaundice beyond what the hospital protocols were already successfully accomplishing.

On February 12, 2018, the initial circulation draft of the proposed rules was presented to the Physician Assistant Policy Committee (“PAPC”) where comments were received regarding the application of phototherapy in the treatment of jaundice by hospital protocol, and regarding the amount and frequency of appropriate training and education to delegates. Based on the comments received from Board members and members of the PAPC as well as written comments provided by interested parties and licensees during the initial circulation of the proposed rules, the following changes were made to the proposed rules:

1. Added definition of vascular laser;
2. Clarified and distinguished definition of phototherapy applied in the treatment of jaundice in infants versus application in the treatment of psoriasis and similar skin diseases.
3. Simplified delegation of phototherapy in the treatment of jaundice in infants by aligning it with hospital standards of care found in their existing protocols and policies.
4. Clarified that the physician evaluation provisions are per type of procedure delegated rather than per procedure, and that the evaluation must occur in person by the physician rather than through video or photograph.
5. Explained the specific education requirements; and clarified that the training must be done per type of procedure rather than per delegating physician.
6. Added a clause that would allow delegates who had been successfully applying a specific type of light based medical device procedure for hair removal to be exempted from education and training requirements if they provided a written certification from a delegating physician stating that the delegate has received sufficient education and training to competently apply that type of light based medical device procedure for hair removal.

**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 consulted with a panel of medical experts to develop the rules. These experts used their own experience and medical texts to guide the development of the rule.

**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 Medical Board considered a multitude of comments across a wide spectrum of opinion regarding the degree of regulation desired and the types of light based medical devices that should be delegated by physicians.

- 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?**

Medical Board staff reviewed the proposed regulations and all relevant Medical Board related Ohio Administrative Code chapters to assure there was no duplication of existing Ohio regulations.

- 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 rule. Board staff will be made aware of the rule's provisions so that the rule 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, licensed practical nurses and cosmetic assistants. The nature of the adverse impact is the eight hours of basic education that must be completed for the delegation of non-ablative

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procedures and laser hair removal. In addition, the physicians will need to have the delegated licensees observe 15 procedures and then provide direct physical oversight of 20 procedures 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. In these proposed rules, the Board is expanding the ability of physicians to delegate the application of certain light based medical devices which helps rather than harms the regulated business community.

**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.

## 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  $1.0 \times 10^6$  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 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. 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 and must be in a location that under normal conditions is not more than sixty minutes travel time from the cosmetic therapist's location.
- (J) “Vascular laser” means 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 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 ~~(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 evaluated the patient in person to determine whether the proposed application of the specific vascular laser is appropriate;

(4) The physician has seen and evaluated the patient in person 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 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 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 (15) 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 (20) 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 (a) 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 (b) and (c) must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physicians;

(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 in person to determine whether the proposed application of ~~a~~ the specific light based medical device is appropriate; ~~and,~~

(4) The physician has seen and ~~personally~~ evaluated the patient in person following the initial application of ~~a~~ 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; ~~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 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 (15) 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 (20) 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 (a) 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 (b) and (c) 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 (2) years through a lawful delegation by a physician, shall be exempted from the education and training requirements of (a), (b), and (c) 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 (60) days after the effective date of this provision, and a copy of the certification shall be retained by each delegating physician and each 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.

(H) 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.

(I) 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 delegation and application of light based medical devices for phototherapy for this treatment is performed pursuant to hospital rules, regulations, policies, and protocols.

(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.