



Light Based Device Rules Frequently Asked Questions

The Ohio Joint Committee on Agency Rule Review (JCARR) recently approved the State Medical Board of Ohio's administrative rules involving Light Based Medical Devices. These rules underwent a thorough and comprehensive course to obtain stakeholder input which was sought at all stages of the process. As a result, changes were made to incorporate public input to the rules. These rules became effective on July 31, 2021. In addition, Section 4731.33, Ohio Revised Code, which outlines the delegation of light based medical devices for hair removal became effective on September 30, 2021. Since the statutory language has some differences from the rule requirements, the rules are in the process of being amended to be consistent with the statutory changes. If there is a conflict between a statute and a rule, the statute takes precedence.

Q1:What is a light based medical device?

A:It is 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.

Q2:Is the application of light based medical devices to the human body the practice of medicine and surgery, osteopathic medicine and surgery or podiatric medicine and surgery?

A:Yes.

Q3:What is an ablative dermatologic procedure?

A:It is a dermatologic procedure that is expected to excise, burn, or vaporize the skin below the dermo-epidermal junction.

Q4:May a physician delegate the use of a light based medical device for an ablative dermatologic procedure?

A: No.

Q5: What is a non-ablative dermatologic procedure?

A: It is a dermatologic procedure that is not expected or intended to excise, burn, or vaporize the epidermal surface of the skin.

Q6: What is a vascular laser?

A: It includes light-based medical devices including lasers and intense pulsed light apparatuses whose primary cutaneous target structures are telangiectasia, venulectasia, and superficial cutaneous vascular structures. The lasers have wavelengths that correspond to the hemoglobin absorption spectrum.

Q7: May a physician delegate the application of a vascular laser for non-ablative dermatologic procedures?

A: Yes, in accordance with Rules [4731-18-02](#) and [4731-18-03\(A\)](#). Ohio Administrative Code.

Questions regarding non ablative lasers:

Q8: Who can perform non-ablative lasers procedures?

A: Rules [4731-18-02](#) and [4731-18-03](#) allow for the delegation of non-ablative vascular lasers by physicians to physician assistants, registered nurses or licensed practical nurses who are deemed to have the appropriate education, training, and supervision.

Q9: What is deemed as the appropriate education and training for physician assistants, registered nurses, or licensed practical nurses to be delegated by a physician to utilize light based medical devices?

A: The amount of education and training that is required for registered nurses and licensed practical nurses delegated to prior to utilizing light based medical devices must include: 8 hours of basic education on specific topics, observation of 15 procedures and the performance of 20 procedures under the direct oversight of the delegating physician. For physician assistants, the supervising physician must follow the requirements of section [4730.21](#) of the Revised Code, in which a physician assistant may only be authorized to perform a service if the supervising physician is satisfied that the physician assistant can perform the service and that service is within the physician's and physician assistant's normal course of practice and expertise.

Q10: Under what conditions can a physician delegate non-ablative laser procedures?

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 to determine that the patient responded well to the initial application of the specific vascular laser;

Q11: What type of supervision must the physician provide to physician assistants, registered nurses or licensed practical nurses who are delegated the use of the vascular laser for non-ablative dermatologic procedures?

A: For delegation to a physician assistant, the supervising physician must be continuously available for direct communication either by being physically present at the location where the physician assistant is practicing or being readily available to the physician assistant through some means of telecommunication and being in a location that reasonably allows the physician to assure proper care of patients.

For delegation to a registered nurse or licensed practical nurse, the physician always provides on-site supervision while the delegee is applying the vascular laser. On-site supervision means that the physical presence of the supervising physician is required in the same location, such as the physician's office suite as the delegate, but the physician's presence in the same room is not required.

Q12: How many physician assistants, registered nurses or licensed practical nurses who are delegated the use of vascular lasers for non-ablative dermatologic procedures may the physician supervise at a time?

A: For physician assistants, the supervising physician may not supervise more than five physician assistants at one time.

For registered nurses or licensed practical nurses, the physician supervises no more than two persons at the same time.

Rules questions regarding Laser hair removal procedures:

Q13: Under what conditions may a physician delegate the application of light based medical devices for the purpose of hair removal?

A: A physician may delegate the application of light-based medical devices for the purpose of hair removal to appropriately trained individuals so long as 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 to determine that the patient responded well to that initial application of the specific light based medical device;

Q14: To whom can physician delegate the ability to perform laser hair removal?

A: A physician assistant with whom the physician has an effective supervision agreement, a registered nurse, a licensed practical nurse, persons formerly licensed by the Medical Board as cosmetic therapists and individuals who have completed a cosmetic therapy course of instruction and passed the required examination.

Q15: Can former licensed cosmetic therapists or those with equivalent education and experience perform laser hair removal?

A: Yes. Section [4731.33\(B\)\(5\)\(b\)](#) and [\(c\)](#) allow for the delegation of laser hair removal by physicians to individuals who were licensed up to and until April 11, 2021, with the State Medical Board of Ohio as a Cosmetic Therapist, or who have completed a cosmetic therapy course of instruction for at least 750 clock hours and passed the Certified Laser Hair Removal Professional Examination administered by “The Society for Clinical and Medical Hair Removal”.

Q16: What if I am in school studying to become a cosmetic therapist?

A: You may continue your studies, the new law means you will be practicing in an unlicensed occupation in Ohio at the end of your education but, can have laser light removal delegated to you if you are deemed qualified by a physician who provides supervision and if you meet the education and training requirements in paragraph (D)(1) of section [4731.33](#) of the Revised Code.

Q17: What are the education and training requirements for cosmetic therapists found in paragraph (D)(1) of section 4731.33 of the Revised Code?

- A:** (1) 8 hours of basic education that includes the following topics: Light-based procedure physics; tissue interaction in light-based procedures; light-based procedure safety, including the use of proper safety equipment; clinical application of light-based procedures; preoperative and postoperative care of light-based procedure patients and the reporting of adverse events;
- (2) Observation of 15 procedures for each specific type of light-based medical device procedure for hair removal that the individual will perform under the delegation; and
- (3) Performance of at least 20 procedures under the direct physical oversight of the physician on each specific type of light-based medical device procedure for hair removal delegated.

Q18: Does the statute provide any other guidance regarding the education and training requirements?

A: Yes. The delegating physician may only perform procedures for observation or oversee procedures which are within the physician’s normal course of practice and expertise.

The delegating physician and the delegate are responsible for documenting and retaining the records regarding the satisfactory completion of training. The 8-hour education requirement is required to be completed only once by the delegate regardless of the number of types of procedures delegated and the number of delegating physicians. The training requirements of observed procedures and performance of procedures under direct physical oversight shall 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.

Q19: Are there exemptions for the education and training requirements?

A: Yes. The following delegates are exempt from the education and training requirements of division (D)(1) of section [4731.33](#) of the Revised Code:

1. A person who before September 30, 2021, has been applying a light-based medical device for hair removal for at least two years through a lawful delegation by a physician.
2. A person who was licensed as a cosmetic therapist under Chapter 4731 of the Revised Code on and before April 11, 2021, if the person was authorized to use a light-based medical device under the cosmetic therapist license.
3. A physician assistant licensed under Chapter 4730 of the Revised Code with whom the physician has an effective supervision agreement.
4. A registered nurse or licensed practical nurse licensed under Chapter 4723 of the Revised Code.

Q20: What supervision is required for physicians delegating laser hair removal in accordance with section 4731.33 of the Revised Code?

A: For physician assistants, the supervising physician must be continuously available for direct communication either by being physically present at the location where the physician assistant is practicing or being readily available to the physician assistant through some means of telecommunication and being in a location that reasonably allows the physician to assure proper care of patients.

For registered nurses and licensed practical nurses, the physician must provide on-site supervision at all times that the person to whom the delegation is made is applying the light-based medical device.

For cosmetic therapists, the physician must provide on-site supervision, unless the cosmetic therapist meets the requirements of paragraph (G)(1) of section [4731.33](#) of the Revised Code. If the cosmetic therapist has completed all of the following, the delegating physician may provide off-site supervision when the light-based medical device is applied for the purpose of hair removal to an established patient:

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 50 hours of training, at least 30 hours of which was clinical experience;
3. The cosmetic therapist worked under the on-site supervision of the delegating physician for 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 is responsible for maintaining documentation of the successful completion of the required training.

Off-site supervision requires the supervising physician to be continuously available for direct communication with the cosmetic therapist during the use of a light-based medical device.

Q21: What is the responsibility of delegates when the patient experiences a clinically significant side effect following the application of the light-based medical device or any failure of the treatment to progress as expected?

A: The delegate shall immediately report the information to the supervising physician.

Q22: Are there legal consequences for unlicensed individuals who have been delegated the ability to practice laser hair removal by a physician and do so improperly?

A: Yes. The application of light based medical devices for hair removal is considered the practice of medicine and surgery. If a cosmetic therapist does not comply with the requirements in section 4731.33 (G)(and (H) of the Revised Code could be found to be committing the offense of the unlicensed practice of medicine.