



Antitrust Referral Analysis Submittal by Board or Commission

Board or Commission: State Medical Board of Ohio

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Referral Topic: Proposed light based medical device procedure rules

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. The CSI office was codified by ORC 107.52 for agency rule review. Additional scope was added in 2017 under ORC 107.56 which describes actions to be reviewed by the CSI Office for determination of approval or disapproval.

Referral Information

1. What is the action/proposed action being taken?

The State Medical Board proposes to amend the light based medical device procedure rules in Ohio Administrative Code chapter 4731-18 by expanding the physician delegation of the application of light based medical device procedures by adding additional types of light based medical device procedures that can be delegated to specified nonphysician operators. To ensure patient safety, the proposed rules strengthen the supervision, education, and training requirements for the delegation of these procedures.

2. In a brief statement explain the factual background, nature, purpose and rationale of the action/proposed action pertaining to this referral.

Light based medical devices include laser and phototherapy devices that direct and, in the case of lasers, amplify light of various wavelengths to affect the structure or function of the human body. The light based medical device rules in chapter 4731-18 became effective in 2000 and 2002. These rules allow physician delegation of: (1) light based medical devices for hair removal to a physician assistant (“PA”), registered nurse (“RN”), licensed practical nurse (“LPN”), or cosmetic therapist (“CT”); (2) phototherapy to “any appropriate person” for treatment of jaundice in infants; and (3) phototherapy to “any appropriate person” for treatment of psoriasis and similar skin diseases.

Since 2002, there have been advances in the practice of medicine using light-based medical devices. As the use of these devices has increased, so have incidents of patient harm when these devices are applied incorrectly. Consequently, the Medical Board proposed updating its rules to recognize the advances in technology and increased use of light based medical devices as well the increased incidents of patient harm. To address these issues, the Medical Board expanded physician delegation while strengthening the supervision, education, and training requirements to protect patients.

On January 17, 2018, the Medical Board circulated its proposed rules to interested parties and licensees and received 47 written comments in response. Among these comments was a comment from an attorney that implied litigation based on the commenter’s perception that the proposed rules would constrain the market for non-ablative weight-loss light-based therapy that chiropractic practitioners desire to use.

Consequently, the Medical Board requests Common Sense Initiative antitrust review of its proposed rules expanding physician delegation of the application of light-based medical device procedures to demonstrate that the Medical Board has sought to responsibly expand the market, rather than constrain it.

The proposed rules allow physician delegation for the following procedures: (1) vascular lasers for non-ablative dermatologic procedures may be delegated to a PA, RN, or LPN; (2) light based medical devices for hair removal may be delegated to a PA, RN, LPN, or CT; (3) phototherapy for the treatment of jaundice in infants may be delegated to an appropriate person based on a hospital’s protocol; (4) phototherapy for the treatment of psoriasis and similar skin diseases may be delegated to a PA, RN, LPN, or certified medical assistant; and (5) photodynamic therapy may be delegated to a PA, RN, or LPN.

3. Please check all of the following that apply as reasons the action/proposed action is subject to review? (ORC 107.56(B)(1))?

Fixes prices or limits price competition;

- Divides, allocates or assigns customers or potential customers or geographic markets in this state among members of the occupation regulated by the boards;
 - Excludes present or potential competitors from the occupation regulated by the board;
 - Limits output or supply in this state of any good or service provided by the members of the regulated occupation;
 - Prohibits offering a particular quality-level of a product or service;
 - Restricts advertising or makes it more expensive or less effective;
 - Substantially reduces the number of firms or providers that can serve a particular set of customers; or
 - Any other activity that could be subject to state or federal antitrust law if undertaken by private persons.
4. Is the action/proposed action explicitly compelled or specifically authorized by statute? If so, please list the statute(s).

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 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.

5. Is the action/proposed action within the scope of the board or commission’s statutorily-delegated general authority to regulate in a given occupation or industry? If so, please describe how it is within scope and reference the statute.

Yes, R.C. 4731.05 gives the Medical Board broad authority to “adopt rules in accordance with Chapter 119 of the Revised Code to carry out the purposes of this chapter.” R.C. 4731.41(A) states that “No person shall practice medicine and surgery, or any of its branches, without the appropriate license or certificate from the state medical board to engage in the practice.” Specific to physician assistants, R.C. 4730.07 empowers the Board to “adopt any other rules necessary to govern the practice of physician assistants, the supervisory relationship between physician assistants and supervising physicians, and the administration and enforcement of this chapter.” Lastly, specific to cosmetic therapists, R.C. 4731.15 authorizes the Board to adopt rules governing cosmetic therapy. Together, these statutes authorize the Medical Board to regulate the practice of medicine and surgery as well as the practice of physician assistants and cosmetic therapists.

6. Please identify the clearly articulated state policy (e.g., health and safety, or consumer protection) in state statute or rule, or any supporting evidence of the harm the action/proposed action is intended to protect against?

The clearly articulated state policy is ensuring patient safety in the practice of medicine and surgery. This state policy is articulated throughout Chapter 4731, particularly in the disciplinary statute R.C. 4731.22.

The application of light-based medical devices without proper credentials, supervision, education, and training poses a risk to patient safety. A nationwide litigation study entitled “Increased Risk of Litigation Associated with Laser Surgery by Nonphysician Operators” details the increased litigation when a non-physician performs laser hair removal. The results of the study state “[d]espite the fact that approximately only one-third of laser hair removal procedures are performed by NPOs [non-physician operators], 75.5% of hair removal lawsuits from 2004 to 2012 were performed by NPOs. From 2008 to 2012, this number increased to 85.7%.” Jalian, H. Ray, Jalian, Chris A., and Avram, Mathew M. “Increased Risk of Litigation Associated with Laser Surgery by Nonphysician Operators.” *JAMA Dermatology* April 2014: 407. (attached).

Problems commonly seen in delegated laser practices include: “(1) burns associated with excessive treatment levels; (2) burns and posttreatment hyperpigmentation associated with treatment of tanned individuals; (3) scarring and hypopigmentation associated with excessive treatment, multiple passes, or cooling excess or failures; (4) delayed healing, erosions, and ulceration associated with untreated herpes simplex infection or impetigo; (5) configurate linear and round patterning of the skin associated with improper treatment resulting in tattooing with the laser hand piece; and (6) corneal and retinal injury due to the inadequate use of eye protection.” Alam, Murad. “Who is Qualified to Perform Laser Surgery and in What Setting.” *Seminars in Plastic Surgery* 2007: 197. (attached).

The State Medical Board of Ohio disciplinary case of Ali Khan, M.D. illustrates the patient harm that can come from the improper delegation of light based medical devices. In short, Dr. Khan improperly delegated a fractional laser to a registered nurse in violation of existing Ohio Administrative Code rules 4731-18-02 and 4731-18-03. (This delegation of a fractional laser would also violate the proposed rules.) The registered nurse improperly applied the fractional laser to the face of Patient 4 which resulted in significant pain to Patient 4 and a waffle-like scar on her face. Dr. Kahn and/or his insurer paid \$85,000.00 to Patient 4 and her husband as a result. The Board permanently revoked the license of Dr. Khan for this conduct as well other violations of the Ohio Medical Practices Act.

Therefore, physician delegation of light based medical device procedures must be done responsibly. Not all light based medical device procedures should be delegated, including ablative procedures which are procedures that excise, burn, or vaporize the skin below the dermo-epidermal junction. Certain procedures require a level of training that only a physician possesses. For other procedures that can be done by nonphysician operators with an appropriate license or credential and thus sufficient medical education, there must be supervision and robust light based medical device education and training to protect patient safety.

The Medical Board’s proposed rules seek to responsibly expand physician delegation of light based medical device procedures with appropriate safeguards in the areas of supervision, education, and training.

6a. How does the action/proposed action address the harm or advance the articulated state policy?

The proposed rules expand physician delegation while concurrently strengthening the supervision, education, and training requirements for delegates. This will expand the market for these services while protecting patient safety.

8. If appropriate, explain the action/proposed action's alleged consistency with state or federal antitrust law, which may include a description of how the action or proposed action may affect the number of competitors and those competitors incentive to compete in amount, quality, variety or other aspects of the good or service offered.

The proposed rules' expansion of physician delegation of the application of light based medical devices is consistent with state and federal antitrust law. The Medical Board proposed rules are expanding the market for non-physician application of light based medical devices, not contracting it. Expanding the market will offer increased access for patients to light based medical device procedures by increasing the types of light based medical device procedures that can be applied by nonphysician providers and thus increasing the supply of providers.

9. What process did the board or commission follow to arrive at its decision to take action/proposed action including public hearings held, public comments invited, studies conducted, data collected interviews conducted, etc.?

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.

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. In response, the Board received 47 written comments.

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 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.

On March 14, 2018, the proposed rules with these changes were presented to the Policy Committee of the Medical Board. The Policy Committee reviewed, discussed, and approved the proposed changes to the rules and also voted to send the amended rules to the full Medical Board for approval to file with the Common Sense Initiative for the antitrust review. Subsequently, the full Medical Board in its March 14, 2018 meeting approved this action.

10. Does the action/ proposed action relate to or depend upon a question that is the subject of a formal opinion request pending before the Ohio Attorney General?

No

11. Provide any other information the board or commission deems appropriate for the Office's review of the action/proposed action.

*Send this completed form, a complete copy of action or proposed action, and any other documentation deemed appropriate for evaluation to CSISReferrals@governor.ohio.gov.

Chapter 4731-18 Surgery Standards-Light Based Procedures

4731-18-01 Standards for Surgery Definitions

~~(A) The surgeon of record in an operative case shall personally:~~

~~(1) Evaluate the patient sufficiently to formulate an appropriate preoperative diagnosis; and~~

~~(2) Select the operation to be performed in consultation with the patient or with a person authorized to act on his patient's behalf; and~~

~~(3) Determine, based on his surgeon's own evaluation, and, as necessary, on consultation with other physicians involved in the patient's care, that the patient is a fit candidate for the operation to be performed; and~~

~~(4) Assure that the patient or a person authorized to act on his patient's behalf gives informed consent before the surgery begins; and~~

~~(5) Comply with division (B)(6) of section 4731.22 of the Revised Code; and~~

~~(6) Perform or personally supervise the surgery, except those portions of the surgery, if any, which are performed or supervised by another qualified surgeon with the informed consent of the patient.~~

~~(B) Management of postoperative medical care is the responsibility of the surgeon of record. The surgeon of record shall fulfill this responsibility by:~~

~~(1) Personally performing the postoperative medical care; or~~

~~(2) Delegating postoperative medical care to another physician or physicians who are qualified by training and experience to provide the level of care required, provided that the surgeon of record shall remain primarily responsible for the patient's overall care unless the patient and the other physician have agreed in advance to shift that responsibility to the other physician; or~~

~~(3) Delegating defined aspects of the postoperative medical care to appropriately trained and supervised allied health care personnel in compliance with applicable standards, provided that the surgeon of record shall retain personal responsibility for the quality of the care rendered by personnel who are under his supervision and control. The surgeon of record shall obtain the patient's fully informed consent, or the consent of a person authorized to act on the patient's behalf, in advance of surgery, before delegating aspects of patient care to allied health care personnel under this paragraph. The surgeon of record need not obtain the patient's informed consent for aspects of care to which the patient has already consented, such as consent to~~

treatment and care by hospital personnel under an informed consent form signed upon the patient's admission to the hospital; or

~~(4) Delegating defined aspects of the postoperative medical care to licensees of other health regulatory boards who are licensed to independently provide the scope of practice and the level of care required, provided that the surgeon of record shall remain primarily responsible for the patient's overall care and must examine the patient during the postoperative period.~~

~~(C) This rule shall not be read to transfer any responsibility which currently rests with any other physician, allied health care provider, or institution to the surgeon of record.~~

~~(D) This rule shall not be read to prohibit or interfere with the appropriate training of medical students and physicians in post graduate training programs, or other personnel.~~

~~(E) The provisions of this rule requiring consultation with or obtaining the informed consent of the patient or a person legally authorized to act on his patient's behalf do not apply to the extent they would prevent the performance of surgery or other procedures under emergency circumstances.~~

As used in this chapter of the Administrative Code:

(A) "Light based medical device" shall mean any device that can be made to produce or amplify electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nm but less than or equal to 1.0×10^6 nm [ten to the sixth power] and that is manufactured, designed, intended or promoted for ~~in vivo~~ irradiation of any part of the human body for the purpose of affecting the structure or function of the body.

(B) "Phototherapy" means the 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.

Original Investigation

Increased Risk of Litigation Associated With Laser Surgery by Nonphysician Operators

H. Ray Jalian, MD; Chris A. Jalian, JD; Mathew M. Avram, MD, JD

IMPORTANCE Controversy exists regarding the role of nonphysicians performing laser surgery and the increased risk of injury associated with this practice.

OBJECTIVE To identify the incidence of medical professional liability claims stemming from cutaneous laser surgery performed by nonphysician operators (NPOs).

DESIGN, SETTING, AND PARTICIPANTS Search of an online national database of public legal documents involving laser surgery by NPOs.

EXPOSURE Laser surgery by nonphysicians.

MAIN OUTCOMES AND MEASURES Frequency and nature of cases, including year of litigation, certification of provider and operator, type of procedure performed, clinical setting of injury, and cause of legal action.

RESULTS From January 1999, to December 2012, we identified 175 cases related to injury secondary to cutaneous laser surgery. Of these, 75 (42.9%) were cases involving an NPO. From 2008 to 2011, the percentage of cases with NPOs increased from 36.3% to 77.8%. Laser hair removal was the most commonly performed procedure. Despite the fact that approximately only one-third of laser hair removal procedures are performed by NPOs, 75.5% of hair removal lawsuits from 2004 to 2012 were performed by NPOs. From 2008 to 2012, this number increased to 85.7%. Most cases (64.0%) by NPOs were performed outside of a traditional medical setting.

CONCLUSIONS AND RELEVANCE Claims related to cutaneous laser surgery by NPOs, particularly outside of a traditional medical setting, are increasing. Physicians and other laser operators should be aware of their state laws, especially in regard to physician supervision of NPOs.

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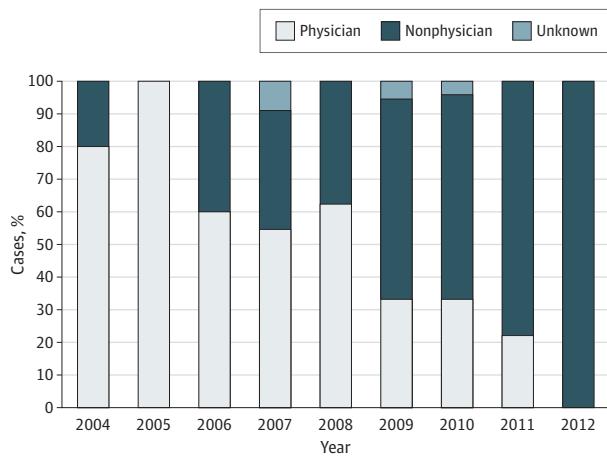
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Cutaneous laser surgery remains one of the most popular elective procedures performed in the United States. Among dermatologic surgeons alone in 2011, more than 1.6 million laser treatments were performed.¹ Many more procedures were performed by physicians in other specialties and by nonphysician operators (NPOs). As the numbers of these procedures increase, a concomitant growth has occurred in laser injury-related litigation.² The practice of delegation to NPOs has accompanied the burgeoning trend toward greater availability of laser surgery and is hypothesized to be in part responsible for the increase in injury and litigation.³ Moreover, the past decade saw the massive expansion of the so-called medical spas, nonmedical facilities offering aesthetic and cosmetic procedures.⁴ Many of these facilities are owned by or

retained by physicians; however, most of the procedures are performed by NPOs of varying certifications as permitted by state regulation. The degree of supervision varies among states, and often the physician supervisor is not required to be on the premises at the time of rendering of services.⁵

Many physicians are increasingly using physician extenders (PEs) within their practice to meet rising demand and falling reimbursements. Among dermatologists, almost 30% reported using a PE within their practice, a 40% increase over the preceding 5 years.⁶ Although no data have emerged regarding increased litigation associated with this practice, legal precedence and numerous investigations are clear on liability.⁷ When a physician delegates duties to a PE, responsibility and liability remain squarely on the supervising physician provided that the services rendered fall within the scope

Figure. Procedures Performed by Nonphysician Operators Increasingly Represent Most Lawsuits



The percentage of cases involving a nonphysician operator is expressed as a percentage of total operators per calendar year. Note the increasing trend toward a larger proportion of nonphysician operators starting in 2008.

of duty of the PE. This holds true for physician supervision of NPOs in the setting of cutaneous laser surgery.²

Despite these trends and clear inconsistencies in state regulations, no study to date has quantified the effect of these practices on medical professional liability claims with regard to cutaneous laser surgery. The objective of this study was to expand on previously published findings in an effort to identify high-risk practices that result in litigation. In addition, the study examines the incidence of litigation related to the performance of laser surgery by NPOs.

Methods

We searched the legal research resource WestlawNext (<http://westlaw.com>) using various keywords as previously reported.² This database is a primary source used by attorneys to gather legal information and is available by subscription to the public. Documents within this database are in the public record. The study was exempt from review, as determined by the institutional review board at Massachusetts General Hospital. An updated search yielded one additional case, bringing the total number of claims concerning injury resulting from cutaneous laser surgery to 175. Of these 175 cases, 75 of the procedures were performed by NPOs. For this study, an NPO is defined as a non-MD, non-DO provider. Because of the nature of the documents within the database, it is difficult to ascertain the exact certification of the NPOs. In an effort to be accurate, various allied health professionals comprised the NPO category. This included operators described as a *registered nurse* or a *nurse practitioner*, as well as terms such as *technician*, *aesthetician*, *assistant*, and *intern*. In addition to previously acquired data, the setting where services were rendered was recorded.

Results

NPO as a Function of Year of Litigation

Of 175 cases identified, the first occurrence of an NPO was in 1999. From January 1999, to December 2012, a total of 75 cases with NPOs were identified. This represents 42.9% of the total cases during the same time frame. Stratification of laser operator by year of litigation revealed a striking trend. From 2004 to 2012, a trend was observed toward an increased proportion of lawsuits stemming from cutaneous laser surgery performed by NPOs. This trend is most notable from 2008 to 2011, our most recent data, during which time the percentage of cases involving an NPO increased from 36.3% to 77.8%. Of the 2 cases in 2012, both were performed by an NPO. These results are summarized in the **Figure**.

Procedures

In line with our previously published data,² the most commonly performed procedure (n = 40) from 2004 to 2012 that resulted in injury and litigation by an NPO involved laser hair removal. Rejuvenation, composed mainly of intense pulsed light treatments, was the second most commonly litigated procedure (n = 7). Among the NPO cases, a notable trend is evident: when expressing the number of NPO cases as a percentage of the total number of cases for the same procedure, 75.5% of laser hair removal lawsuits from 2004 to 2012 were performed by an NPO. This number is even more dramatic in the years 2008 to 2012, when 85.7% of all laser hair removal lawsuits were performed by an NPO. From 2010 to 2012, a total of 90.0% (18 of 20) of laser hair removal cases were performed by an NPO. The remainder of the litigated procedures by NPOs and the proportion of total cases are given in **Table 1**.

Location of Services

From 1999 to 2012, a total of 64.0% (n = 48) of the NPO cases arose in a nonmedical practice setting. These include medical spas and other nonmedical facilities offering cosmetic services (eg, salons, spas, etc). In 2008 to 2011, NPO procedures performed in medical spas represented almost 80% of lawsuits. Of the 2 cases in 2012, one was performed in a medical spa setting and the other in a physician office. When looking at the type of procedure performed in this setting, most of these cases were laser hair removal procedures. From 2008 to 2012, a total of 68.6% (n = 24) of laser hair removal litigation cases involved an NPO in a medical spa setting. These results are summarized in **Table 2**.

Specific Allegations

Not surprisingly, the injuries sustained following laser surgery by NPOs and the causes of action in these cases mirror those previously reported by our group.² However, the specific allegations in these cases offer insight into various liabilities imposed on physician supervisors.

It is necessary to first examine the 2 different forms of liability (direct and vicarious) that a physician could face arising from allegedly improper laser treatment. A physician is directly liable for any negligence that can be attributed to an

Table 1. Cases Involving Laser Procedures Performed by Nonphysician Operators

Procedure	No./Total No. (%)		
	All Cases ^a (n = 106)	All Cases by Nonphysician Operators 2004-2012 ^b	All Cases by Nonphysician Operators 2008-2012 ^b
Hair removal	40 (37.7)	40/53 (75.5)	30/35 (85.7)
Rejuvenation ^c	7 (6.6)	7/22 (31.8)	7/22 (31.8)
Leg veins	3 (2.8)	3/7 (42.9)	3/7 (42.9)
Vascular ^d	1 (0.9)	1/4 (25.0)	1/4 (25.0)
Tattoo	1 (0.9)	1/4 (25.0)	1/4 (25.0)
Scar	2 (1.9)	2/2 (100.0)	2/2 (100.0)
Pigmented lesion	1 (0.9)	1/1 (100.0)	1/1 (100.0)
Other ^e	2 (1.9)	2/3 (66.7)	2/3 (66.7)

^a All cases from 2004 to 2012, including physician, nonphysician, and unknown operators.

^b All nonphysician operator cases expressed as a percentage relative to the total specific procedure cases with all operators.

^c Most with an intense pulsed light device.

^d Includes treatment of vascular lesions and telangiectasia.

^e Includes one case related to fat removal and one case of skin tightening.

Table 2. Setting of Cases Involving Laser Procedures Performed by Nonphysician Operators

Year	No./Total No. (%)			
	Medical Spa	Physician Office	Unknown Setting	Laser Hair Removal ^a
1999-2012	48 (64.0)	25 (33.3)	2 (2.7)	33/48 (68.8)
2004-2012	41 (70.7)	16 (27.6)	1 (1.7)	29/40 (72.5)
2008-2012	36 (76.6)	11 (23.4)	0	24/35 (68.6)

^a Number of cases performed by nonphysician operators in a medical spa setting relative to the total procedures performed by nonphysician operators in all settings.

individual capacity (ie, the personal failure to perform his or her duties at the requisite standard of care). A physician's duties often extend beyond the laser procedure; for instance, a physician may be directly liable for any negligent hiring, supervision, or training and so forth.

Conversely, a physician is vicariously liable for the negligence of his or her employees. A physician's vicarious liability is rooted in the doctrine of *respondeat superior* (Latin for "let the master answer"). This common law doctrine is often used to hold the employer responsible for the actions of his or her employees if and when the employee is acting within the scope of his or her employment. The rationale underpinning the application of vicarious liability to an employer is 2-fold. First, an employer has the ability and duty to control his or her employees. Second, presumably an employee is performing duties that will result in a benefit to the employer and in so doing is acting under the direction or authority of the employer. Therefore, in a medical malpractice context, a physician can be vicariously liable for the negligence of his or her subordinates, including nurses, NPOs, and other staff.

Almost all of the malpractice cases arising from the negligence of NPOs are coupled with vicarious liability claims against the employer, often a medical spa but at times a physician owner. Notably, 25 of 58 cases (43.1%) with NPOs from 2004 to 2012 represented instances in which no direct physician supervisor was identified. In these cases, the facility was often named as the defendant. As for a physician's direct liability in NPO cases, by far the most common specific allegation (n = 27) was failure to supervise the delegate. Failure to supervise represents the physician's failure to properly oversee the procedure. Failure to train and hire appropriate staff was the second most common specific allegation (n = 23). In addition to these allegations, negligent entrustment (n = 2) was alleged against the physician employers in their individual capacity. Negligent entrustment arises when one party (the en-

trustor) is held liable for providing another individual (the entrustee) with a potentially dangerous instrument. In this context, a physician can be held liable for providing an NPO with a laser if this instrument is used for a procedure that results in injury to a patient. The physician liability is predicated on the fact that a reasonable person in like circumstances would not have entrusted the NPO with the equipment. A summary of specific allegations (where available) relating to injury sustained as a result of laser surgery by NPOs from 1999 to 2012 includes the following: failure to properly hire, train, or supervise staff (n = 27); failure to properly perform treatment or operate a laser (n = 23); failure to conduct a test spot (n = 10); lack of a license to perform a procedure (n = 6); failure to recognize or treat an injury (n = 5); and negligent entrustment (n = 2). As can be seen from the foregoing definitions, a physician's direct liability is predicated on his or her negligence, not the negligence of his or her employee or agent.

Discussion

Physician delegation of laser surgery has grown significantly during the past decade. In addition, nonphysician-supervised NPO laser surgery is being performed legally in many states at nonmedical facilities. Data on the safety of NPO performance of cutaneous laser surgery are lacking in the medical literature. Most important, a clear trend demonstrates a dramatic increase in the number of lawsuits associated with NPO performance of laser surgery. The NPOs comprise a vast diversity of operators, including nurse practitioners, registered nurses, medical assistants, electrologists, and aestheticians, among others. In 2011, the latest year with a presumed complete data set, 77.8% of the cases involved an NPO. In addition, of the cases with NPOs, almost two-thirds occurred outside of a traditional medical practice. From an examination of

the specific allegations available in this study, the following 2 themes emerged: (1) both vicarious and direct liability of the supervising physician and (2) the prevalence of nonmedical personnel failing to perform procedures commensurate with the standard of care, including recognizing and treating complications.

We propose that the overall trend in increased litigation for laser surgery is in part explained by greater numbers of NPOs performing these procedures, in particular those practicing without direct supervision in the medical spas. This is the first study to date to offer such quantitative evidence. Of the procedures performed, laser hair removal accounted for most of these cases. Indeed, laser hair removal is the most frequently performed laser procedure in the United States.⁸ However, if one takes into account the number of procedures performed by operators (physician vs NPO), the data become even more compelling. Only one-third of laser hair removal procedures in 2012 were performed by an NPO; the remaining two-thirds were performed by physicians.⁸ Despite the fact that physicians perform most laser hair removal, 85.7% of laser hair removal lawsuits in our study from 2008 to 2012 are cases involving an NPO. In 2011, a remarkable 90.9% (10 of 11) of laser hair removal litigation was against NPOs. One way to interpret these data is that some increased inherent risk of injury exists with an NPO.

The inconsistency and ambiguity of the state laws exemplify the lack of uniformity of the practice of delegation. For example, in Maine only a physician may operate a laser for hair removal. At the other end of the spectrum, Nevada as of June 2011 had no regulations regarding the use of a laser. In addition to the ability to delegate these procedures is the degree of supervision required. Some state statutes are explicit in stating the need for a written protocol, the requirement to appropriately train and document the training of personnel, and the necessity for adequate supervision. Many physicians “lend” their medical license to these facilities without meeting the legal requirements for supervision. In line with this, California recently passed a bill (California Assembly Bill 1548, Chapter 140) that increases penalties for illegally owning and operating a medical spa, with fines up to \$50 000 and a maximum of 2 to 5 years in state prison. The lack of overarching federal law makes it difficult to uniformly require qualifications of personnel allowed to render laser treatments. Despite appropriate certification, regulations regarding appropriate training are ambiguous and are subject to interpretation. Because laws and regulations are constantly evolving, it is imperative for physicians who use PEs to be up to date. Current guidelines can be found at state medical board and state legislature websites.

In the correct setting, with close on-site supervision and appropriate training, the use of NPOs can prove to be a fruitful, productive, and safe environment for patients. Perhaps a larger issue is the role of NPOs, as well as physicians without adequate training, in the operation of a laser. Technology related to laser surgery has evolved rapidly since the description of selective photothermolysis by Anderson and Parrish⁹

in 1983. Despite the propagation of nonmedical facilities performing these procedures, the tremendous amount of physics and medicine related to cutaneous surgery should not be overlooked. The American Society for Dermatologic Surgery Association position promulgates the use of energy devices capable of altering or damaging living tissue to physicians who are “trained appropriately in the physics, safety, and surgical techniques involved in the use of energy devices capable of damaging living tissue prior to performing procedures using such devices.”¹⁰ Moreover, in the setting of delegation, a physician “should be fully qualified by residency training and preceptorship or appropriate course work prior to delegating procedures to licensed allied health professionals and should directly supervise the procedures. The supervising physician shall be physically present on-site, immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed.”¹⁰ Finally, the position statement underscores the need for “appropriate documented training in the physics, safety, and surgical techniques of each system. The licensed allied health professional should also be appropriately trained by the delegating physician in cutaneous medicine, the indications for such surgical procedures, and the pre- and post-operative care involved in treatment.”¹⁰

Several limitations are inherent in conducting research using a legal database. First, although it is a massive data bank, only one legal database was searched. Cases within the database are those in which some form of legal action was taken and exclude complaints handled outside of the judicial system (ie, third-party arbitration through a malpractice carrier). This is likely to have excluded many frivolous claims with little merit. Second, the query was a retrospective review and was limited by the search terms selected; it is likely that some decisions exist that did not contain the searched terms. Third, these legal pleadings are layman documents (ie, not medical records), and the veracity of the facts was assumed to be true. Furthermore, layman terms may have eluded a database search for the purposes of this study. Fourth, because of the limited number of cases with NPOs for certain procedures, it is difficult to interpret the trends for less commonly performed surgery. Nonetheless, the actual data likely understate the true incidence of NPO laser complications. Generally, plaintiffs’ attorneys do not pursue litigation against uninsured operators. Unlike physicians, NPOs (especially in a nonmedical office setting) are less likely to possess liability insurance that can satisfy a potential malpractice or other legal judgment.

A dramatic increase in litigation has been filed against NPOs performing cutaneous laser procedures in medical and non-medical office settings. This has important implications for the safety of patients undergoing these procedures. When a physician delegates duties to a PE, responsibility and liability remain squarely on the supervising physician provided that the services rendered fall within the scope of duty of the PE. This holds true for physicians supervising NPOs in the setting of cutaneous laser surgery. Given the increase in NPO laser surgery procedures and a parallel trend in greater frequency of lawsuits, further studies are needed to examine this troubling trend in laser safety.

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Study concept and design: H. R. Jalian, Avram.

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Conflict of Interest Disclosures: Dr Avram serves as a member of the medical advisory board for Zeltiq Aesthetics, Inc, and of the scientific advisory board for Cytrelis Biosystems, Inc. He has served as a consultant for Unilever, Zeltiq Aesthetics, Inc, and Allergan within the past 12 months. No other disclosures were reported.

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NOTABLE NOTES

The Men or Women Behind Nevi: Alfred Guido Miescher

Fabrizio Vaira, MD; Gianluca Nazzaro, MD; Carlo Crosti, MD; Stefano Veraldi, MD

The man behind Miescher nevus is Alfred Guido Miescher. He was born on November 4, 1887, in Naples, Italy. His mother was Marietta Berner, and his father, Max Eduard Miescher, was a businessman. He was the nephew of Johannes Friedrich Miescher (1844-1895), professor of pathophysiology at the University of Basel, Switzerland, and discoverer of nucleic acids. After the father's death, he followed his mother to Basel, her hometown, where Guido completed his school.

He started his studies in engineering at the *Eidgenössische Technische Hochschule* in Zurich, Switzerland, and then switched to medicine, studying in Basel, Zurich, and Munich, Germany.¹ Working as an assistant of the dermatologist Bruno Bloch, he wrote his thesis on a case of mycetoma. In 1933, after the death of his mentor, Miescher become professor and director of the University Dermatology Clinic in Zurich. Miescher was an excellent clinician, and he was passionate about clinical dermatology and Dermatopathology. Indeed, he said that "Dermatology is more than morphology."¹

In his original landmark work, *Histologie de 100 cas de naevi pigmentaires d'après les methods de Masson*, published in 1935, Miescher studied 100 hemispherical naevi found mostly on women's faces. They are dome-shaped papules in which melanocytes are distributed mostly endophytically, often in a wedge, and they reach the deep reticular dermis.^{2,3} Miescher was a pioneer in the treatment of skin diseases with phototherapy and of cutaneous tumors with ionizing radiation. Indeed, he helped to improve dermatological radiotherapy, through determining the safest doses and innovative frac-

tionation schemes to reduce the toxic effects. Miescher was skilled in identifying new aspects of already known diseases. He reclassified granulomatosis disciformis chronica et progressiva, and, in 1945, he was the first to describe the cheilitis granulomatosa, subsequently also called Miescher cheilitis.

His students said that he cared about only 3 things: dermatology, music, and mountains. Miescher was a gifted cellist and a lover of mountaineering, as well as an illustrious dermatologist. He bravely climbed numerous Swiss peaks. But his most important venture was an expedition to the Caucasus Mountains. Miescher was the first person to climb Mount Elbrus (5629 m) and ski down. After a life full of medical and sporting achievements, he fought against the cancer and died in 1961.

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Who Is Qualified to Perform Laser Surgery and in What Setting?

Murad Alam, M.D., M.S.C.I.¹

ABSTRACT

Laser and light procedures are commonly delegated to nonphysician providers. The purpose of this report is (1) to summarize the factors that determine how such delegation may occur, (2) to analyze the potential pitfalls and problems associated with delegation, and (3) to propose alternative approaches that may improve the delegation process to maximize patient safety while not unreasonably restricting nonphysician provision of laser services.

KEYWORDS: Delegation, pitfalls, alternatives, patient safety, training

HISTORICAL OVERVIEW: INCREASING CONCERNS ABOUT DELEGATION

Prior to 1998, there exist few if any published reports regarding nonphysician performance of laser procedures.¹ Presumably, this dearth stemmed from the very small size of the laser business, which was the province of a few subspecialist physicians. Moreover, many commonly used lasers, such as those for hair removal and tattoo or pigment removal, had only recently been introduced, and their parameters of use were not standardized. The landscape has changed. As early as 8 to 10 years ago, reports documented the increasing tension between dermatologists and electrologists over the training required to perform laser hair removal, with dermatologists advocating that licensed physicians should supervise and be on-site; states, such as Texas, that do not require licensing for electrologists were a particular area of concern.^{1,2} Yet concurrently, data was presented to show that “properly trained” nurses had no greater risk than physicians of inducing undesirable outcomes like pigmentation change and blistering after laser hair removal with long-pulsed alexandrite laser.³ Most recently, the American Society for Dermatologic Surgery

(ASDS) reported that more than 100 million laser and light-source cosmetic procedures were performed by its members.⁴ And the increase appears to be even greater among nonphysician providers. More ominously, studies suggest that a proportionately greater amount of complications are arising from dermatologic care delivered by physician extenders. Nearly 53% of 488 dermatologists surveyed in Texas in 2004 reported seeing increased complications associated with delegation to nonphysicians, with 33% of those surveyed asserting that they knew of such complications arising in the absence of a supervising physician on-site during treatment delivery.⁵ This confirmed earlier results of a survey of 2400 members of the ASDS in 2001, which ascribed the preponderance of posttreatment patient complications to “nonphysician operators,” including cosmetic technicians, estheticians, and workers in medical/dental offices who performed procedures for which they were not trained or during the performance of which they were inadequately supervised.⁶ A growing body of evidence suggests that nonphysician provision of laser services and insufficient physician oversight of extenders may be jeopardizing patients, unnecessarily raising complication

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rates, and leaving dermatologists vulnerable to public censure and legal liability.^{4,7} The American Society of Laser Surgery and Medicine (ASLMS), which has a diverse membership, including physicians from various specialties, has included policies pertaining to supervision and training in its white paper entitled "Procedural Skills for Using Lasers in General Surgery," which was approved by the board of directors of this organization on April 6, 2006. Specifically, under the section on laser utilization (general requirements and administrative controls, p. 7), the following sections are relevant:⁸

- A. Lasers are utilized only by individuals who have been credentialed for the use of specific types of lasers. The individual **MAY NOT** [bold in original] utilize laser technology for purposes and scenarios for which she/he does not have active privileges and appropriate training and experience.
- B. Individuals are not exposed to the useful active laser beam except for healing arts purposes and only when such exposure is authorized by a properly credentialed individual.
- C. Registered Nurses, Licensed Practical Nurses, and Technicians operate lasers only after completion of an acceptable program of certification. Personnel are certified to operate specific lasers (e.g., CO₂, KTP, Nd:YAG, etc.).

HOW DELEGATION WORKS NOW

At present, laser procedures are delivered in various venues. These include the outpatient offices of physicians trained in laser-relevant specialties and of physicians in other specialties. Various personnel may be involved in laser procedure delivery. At one extreme, all laser procedures may be delivered by the laser-trained specialist physician. Alternatively, laser services may be delegated to a less trained medical provider, but the physician of record may be involved in pretreatment consultation. At the other extreme, nonphysician personnel may provide laser services to patients without the physician ever having met or seen the patients or having acquiesced to the treatment plan. In some cases, physicians, especially those in nonrelevant specialties, may not be intimately familiar or expert with laser procedures themselves and may hire nurses or other caregivers who have been trained in laser procedures elsewhere to provide these services. Laser services would thus be a form of practice extension, or internal referral, for such physicians.

When laser services are delegated in a physician's office, the delegation may be to a licensed physician; or to a high-level nonphysician provider, like a physician's assistant, clinical nurse practitioner, or registered nurse; or to a low-level nonmedical provider, like a licensed practical nurse, surgical assistant, or medical assistant; or

to a nonmedical provider, like an aesthetician. The potential benefits of delegation to a licensed but less trained and possibly non-board eligible physician include protection of the delegating physician from malpractice claims. The benefits of delegation to a high-level nonphysician provider include the high levels of technical competence and reliability of such personnel. Lower-level nonphysician providers may, however, be a more economical choice, and they may be almost as successful in laser treatment if they have prolonged experience. A nonmedical provider, like an aesthetician, can be useful if the individual is also able to perform other non-laser procedures that may be valuable to a practice.

Laser services that occur outside of a physician's office are usually still associated with delegation, albeit more tenuous and distant delegation. Free-standing spas that provide medical services and nonmedical personal services may be staffed exclusively with nonphysician and even nonmedical personnel but may be loosely supervised by a licensed physician at another site. The primary purpose of a spa may be to function as a free-standing profit center, or it may be designed to capture patients and "up-sell" them to procedures available at the managing physician's primary office. In some cases, a spa may be part of a regional or national network of spas, operated by an overarching commercial entity and managed centrally by a medical director.

The degree of trained physician oversight at spas varies considerably. A physician may be present daily or more commonly a few times a week or month. The spa staff may be trained by and responsible to the delegating physician or they may be hired and managed by a business entity. The delegating physician, in some cases, may never come to the spa and may be only minimally available to the spa personnel by telephone or other means. Indeed, it is possible that the delegating physician may have only a legal connection to the spa as a consultant or medical director and may not even be trained in the provision of laser services he or she ostensibly supervises.

PITFALLS AND PROBLEMS ASSOCIATED WITH DELEGATION

Delegation of medical functions is a widely recognized and approved physician responsibility and privilege; however, in the context of cutaneous laser procedures, delegation can be problematic to the extent that it results in suboptimal care, insufficient caregiver oversight, and increased risk to patients of treatment-associated adverse events.

THE PURPOSES OF DELEGATION

In order to appreciate the limitations of delegation, it is useful to review the reasons why delegation occurs.

These purposes include legislatively acknowledged reasons as well as unrelated motives.

Some reasons for delegation are noncontroversial and intertwined. These include (1) increased efficiency of patient care; (2) patient convenience; (3) patient safety; and (4) cost-effectiveness. Increased efficiency may derive from a physician not performing all parts of a medical service himself or herself. Some of the functions intrinsic to patient care, like rooming patients, eliciting part of the medical history and examination findings (e.g., weight, blood pressure), and preparing surgical trays, may be well within the scope of practice of nonphysician medical personnel, who may be specifically trained to perform these. In fact, nonphysician personnel, by dint of specialized training and experience in such activities, may be faster and more accurate in performing them than the delegating physician. By delegating parts of the patient interaction that are uniform, repetitive, and less likely to require clinical judgment, the physician may also have more time to focus on other aspects of the patient interaction. Overall, delegation would thus provide the patient with a potentially quicker office visit, in which the physician would be able to direct his or her attention to the most sophisticated concerns.

Needless to say, delegation of this type would also enhance patient convenience. A briefer visit would be more convenient. Even if the visit were not briefer, the structured nature of the delegated functions would ensure that information was processed systematically and without omissions. Patient safety would be improved to the extent that delegation resulted in redundancy. That is, whereas a nonphysician provider may perform some key functions of a medical visit, the physician would retain overall responsibility and would revisit issues that were unclear or insufficiently described. This repetition, which is at the heart of the medical model in the United States, would ideally minimize errors of omission.

Finally, a model in which routine activities were delegated to nonphysicians would be cost-effective. Because physician time is usually the most expensive element of office visits, not using physician time for delegated functions would reduce overall cost. Yet because the delegated tasks would be simple and standardized, overall quality of care would not suffer. Reduced cost associated with constant effectiveness would imply improved cost-effectiveness.

Beyond these generally accepted reasons for delegation, there are other motives that may be operable in certain situations. To the extent that the physician or medical director is the managerial head of the office-based practice, he or she may be positioned to maximize the best interests of the physician. At times, these interests may be in conflict with the best interests of the patient.

The best interests of the physician may include (1) maximization of revenue through leverage; (2) max-

imization of revenue through provision of delegated low-price services; (3) ability to price out-of-pocket procedures competitively; (4) passive income; (5) incentivization of nonphysician providers; (6) reduced direct patient care; and (7) reduced overall work hours.

Revenue maximization is a goal of physicians in office-based practices as growth in revenue results in a proportionate increase in physician compensation. More specifically, revenue objectives include both higher total revenue and wider gross margin, the difference between revenue and expenses. Higher total revenue is achieved when the physician delegates revenue-generating activities to another nonphysician provider. Assuming the physician continues to serve the same number of patients as before, such delegation results in a greater total number of patients served by the physician and the additional provider together. Further, it is possible for the physician to delegate to more than one nonphysician provider. In some states, there are limits to the number of physician's assistants or nurse practitioners to whom a given physician can delegate. Such high-level nonphysician providers can be highly productive, as they can manage patients independently, and work at a rate only slightly below that of the delegating physician. Other lower-level nonphysician providers may be less productive, but they are also compensated at a lower level. To maximize the financial leverage of a practice, a delegating physician would continue to add high-level and low-level nonphysician providers until one of the following occurred: (1) licensing rules prohibited addition of more such providers; (2) the physician was not able to manage and supervise additional providers safely; (3) the marginal revenue generated by the addition of another nonphysician provider would be less than the cost, including salary and expenses, associated with the addition of such a provider.

Notably, the addition of a physician assistant or nurse practitioner can be a turn-key process, whereby the delegating physician can derive additional income without much additional supervisory function, yet low-level providers can be highly financially productive as well. Much less expensive in terms of salary, such low-level providers may require special, local training from the delegating physician but thereafter may be able to accomplish many of the same functions as a high-level provider. Moreover, rules may not restrict the number of low-level providers who may work with a given physician.

The availability of low-cost but laser-trained low-level providers may facilitate practice expansion. Thus, some laser services, such as laser hair removal and microdermabrasion, may be priced at a point too low for direct physician delivery. Were the physician to perform such services directly, he or she would forego in opportunity cost the provision of other more lucrative services. And if the physician raised the price of these

usually low-priced services to make them more worth physician time, the price may become too high for the market, and volume may fall drastically as a result. In some communities, the commodification of routine laser services like laser hair removal has become so extreme that only very-low-cost, low-level nonphysician providers can deliver such services at a competitive price. Again, though these services may not be provided by a physician, it would be in the delegating physician's financial interest to ensure that some personnel in the practice offered these at a competitive price as long as the difference between price and cost of service provision remained a positive quantity. In some cases, it may even be expedient to reduce prices below the median price in a given market in a bid to increase volume, and hence total revenue, more markedly.

The previous discussion assumes that the physician will not reduce physician time as a result of delegation and that delegation will instead increase physician revenue; however, this may not be the case, and the physician may prefer to use delegation as a means of reducing physician effort while maintaining a similar compensation level. Addition of high-level nonphysician providers can result in substantial passive income for the delegating physician because the gross revenue garnered by such personnel is slightly less than that of a free-standing physician, but the compensation of such personnel is substantially lower than physician compensation. It has been argued that in some cases, physician's assistants and nurse practitioners may merely function by appropriating patients already presenting to the practice (i.e., "cannibalizing, feeding off the physician") rather than creating new business (i.e., "rainmaking"). Were this to be true, it may still be the case that physician effort decreased as the high-level providers delivered care while physician income remained constant. It may also be the case that several years of training may be required to ensure that even high-level providers function efficiently and safely with minimal physician supervision; presumably this would postpone the point at which the physician could decrease his or her involvement in day-to-day practice operation.

One potential problem of delegating to numerous high- and low-level providers is the issue of diminishing returns, raised above. That is, a means must be found to consistently increase the size of the pie, the practice's patient base, rather than to merely reallocate ever smaller pieces of the pie to a growing number of providers. This problem is addressed via incentivization of nonphysician providers. The compensation of such providers is typically tied to their clinical productivity, with escalating payments associated with levels of financial productivity above the median for a particular provider type. Safeguards may be implemented by internalizing within the compensation model both quality of care benchmarks and good citizenship vis-à-vis other providers.

Methods, such as noncompete covenants and retention bonuses, must also be implemented to ensure long-term commitment of nonphysician providers to the practice. High-level providers, in particular, may be highly mobile because once they are laser-trained, they can function quasi-independently. Hence, such high-level providers are able to affiliate with physicians from various specialties, including physicians who may lack laser expertise themselves and who consequently may be willing to agree to a better compensation scheme. The physician initially training high-level providers may wish to avoid losing them to other physicians for at least two reasons: (1) loss of the time required to train these providers and the need for time to find and train new ones, and (2) competition with the departing providers once they are employed by another physician.

One special case of delegation occurs when a laser-trained physician in a relevant medical specialty delegates to a licensed physician without specialty certification. Such a licensed physician is at the lowest training level for a physician but obviously more qualified than a high-level nonphysician provider. As such, a licensed physician of this type may function in a manner similar to a high-level nonphysician provider: he or she may be compensated at a level lower than the laser-trained specialist and garner almost as much revenue performing slightly lower-price procedures than the specialist. The laser-trained specialist who is the marquee draw for the practice may pocket the difference. For elite laser practices that pride themselves on only having physician providers, a licensed physician may offer the benefits of delegation without the stigma of nonphysician providers. Additionally, there is no limit to how many such licensed physicians can be employed by a practice, and their malpractice coverage may be sufficient to completely protect the specialist physician who owns the practice.

All of the above reasons for delegation are also operative in a spa environment, where the leadership may not be an on-site physician proprietor but rather a distant physician proprietor or a corporate owner. In the case of a spa, the financial incentives for delegation are further enhanced by the nature of the business model, which resembles a retail store rather than a medical practice. There may be no physicians present at most times, and there may even be a dearth of medical personnel. Most spa services may be provided by aestheticians and nonmedical nonphysician providers, who are not inculcated in the need to ensure patient well-being. To a greater extent than in a physician practice, service providers may be compensated on an incentive basis.

POTENTIAL DANGERS OF DELEGATION

The problems associated with delegation of laser services are secondary to imprudence in delegation, as motivated

by the reasons outlined above. Excessive delegation can result in (1) impaired patient safety, including (a) increased frequency of avoidable adverse events and (b) failure to treat adverse events appropriately and in a timely manner; (2) provision of unnecessary or inappropriate laser services; (3) overtreatment; and (4) subordination of patient well-being to financial productivity of the practice.

These potential problems are easy to predict but difficult to avoid. As previously discussed, profit maximization suggests that delegation should continue until the marginal revenue associated with adding an incremental nonphysician provider (or licensed physician) becomes negative. It is not, however, necessary that the point of financial nonviability coincides with the safe limits of adding personnel. That is, before the profit maximization point is reached, safety may be compromised, as (a) a given physician supervises more nonphysician providers than he is able to closely monitor, and (b) the turnover rate of nonphysician providers becomes too great to ensure adequate training. Problems that have been commonly seen in delegated laser practices include the following: (1) burns associated with excessive treatment levels; (2) burns and posttreatment hyperpigmentation associated with treatment of tanned individuals; (3) scarring and hypopigmentation associated with excessive treatment, multiple passes, or cooling excess or failures; (4) delayed healing, erosions, and ulceration associated with untreated herpes simplex infection or impetigo; (5) configurate linear and round patterning of the skin associated with improper treatment resulting in tattooing with the laser hand piece; and (6) corneal and retinal injury due to inadequate use of eye protection. Some of these problems, like hyperpigmentation, will eventually resolve, but hypopigmentation, scar, and configurate scarring can be persistent and disfiguring. Rampant infection can result in functional loss, including permanent impairment of facial sensory structures.

The problem of impaired safety is exacerbated by the lack of general dermatologic training among nonphysician providers of laser services. In general, low-level and even some high-level nonphysician providers are trained mostly in the technique of laser service delivery, with lesser training in the management of adverse events, and little or no training in general cutaneous medicine. Adverse events, and especially unusual adverse events, may be recognized late by such providers, who may then treat them incorrectly. Especially when physician supervision is light, incorrect treatment may continue for some time until the problem has been worsened and permanent sequelae may be inevitable. It is a truism in cutaneous laser therapy that the firing of a laser hand piece is a trivial activity; it is everything but the actual treatment, including patient selection, parameter selection, and recognition and management of undesirable

outcomes, that requires judgment and training. In the spa environment or in a multiprovider practice, the pressure to "convert" all consultations into treatments may result in poor patient selection, which may dramatically increase the rate of adverse events.

Incentivization of nonphysician providers to maximize revenue generation can increase the risk of adverse events by (1) hurrying preoperative evaluation and laser treatment and (2) encouraging the treatment of patients who may be poor laser candidates. To the extent that nonphysician providers have a skewed financial incentive structure, wherein they are more rewarded for revenue generation than penalized for adverse events and patient dissatisfaction, the impetus to increase business may dominate. The result is increased risk for the patient and for the delegating physician, who may have medicolegal responsibility for problems accruing from delegated services.

Beyond adverse events, incentivization may lead to unnecessary treatments motivated by the desire to charge for the same. Indeed, it may be more revenue generating to systematically undertreat patients to ensure that they return for more visits. Subtherapeutic treatments may also reduce the risk of adverse events when laser treatments are delivered by minimally trained nonphysician providers. Although undertreatment is unlikely to cause irrevocable physical injury, it is a form of fraud that wastes patients' time and money.

OPTIMIZING DELEGATION OF LASER SERVICES: MAINTAINING SAFETY WHILE RUNNING A BUSINESS

A preeminent objective of medical care is safety of the patient. To this end, delegation of laser services should be performed in such a manner that patient welfare is not subordinated to the profit motive.

At the same time, safety is a relative goal, and perfect safety cannot be ensured during any medical procedure. The goal, therefore, becomes structuring of incentives so that safety is not only philosophically desirable but is also in the personal best interests of the personnel delivering medical services.

An incentive that is potentially antithetical to patient safety is the desire of the service provider to profit from delivery of laser services. Given that compensation for cosmetic laser procedures is usually fee-for-service, overall revenue can be maximized by increasing charge per procedure or minimizing staff and supply costs per patient. The prevailing charge is a function of the balance between supply and demand and cannot be modified by a single practice that does not have market (i.e., monopoly) power. On the other hand, minimization of practice costs per patient can be accomplished by (1) using less staff time per patient, (2) using less skilled staff per patient, (3) reducing staff

training and supervision, (4) using less space and supplies per patient, and (5) enlarging the practice by recruiting more patients. Of these cost-minimization strategies, reduction in staff expense is the most fruitful because staff expense tends to account for the majority of practice overhead.

Because each of the above cost-minimization strategies carries the hazard of impaired patient safety, it is necessary to implement controls to ensure a minimal standard of safety for patients. Such controls can be practice-directed or provider-specific. Practice-directed incentives, like fining instances of inappropriately low staffing levels, can incentivize practices to maintain certain safety benchmarks. Provider-specific incentives consist of such mechanisms as malpractice expense, professional licensing requirements, and maintenance of professional reputation among peers, which are jeopardized by a provider's poor safety record.

Before considering a specific arrangement of incentives to maximize safety, it is instructive to review the hierarchy of personnel who may provide laser services. Of course, there are individual differences in motivation, training, and competence, but categories can nonetheless be distinguished. In particular, laser-trained physicians in a relevant medical specialty (including those who are fellowship-trained, fellows-in-training, or pioneers in the field) are most qualified to deliver cutaneous laser services safely. They have the most didactic training, have advanced clinical training, have a base of medical training in a relevant specialty, and comprise much of the research leadership in clinical and basic investigation. After this category, there are laser-trained physicians in nonrelevant specialties. These may lack a foundation of knowledge in cutaneous medicine but may have relevant training in the operation of specific laser devices. They would be superior to laser-trained licensed physicians, who may have no more training in laser, but they lack a residency in clinical medicine. Below this category would be both non-laser trained physicians in nonrelevant specialties and basic researchers in light and optics; although these groups may have excellent clinical and research skills, respectively, they have no specific skills in the provision of cutaneous laser services to patients. Among nonphysician providers, the high-level providers would be laser-trained physician's assistants, clinical nurse practitioners, and registered nurses. Each of these have substantial and rigorous training in the care of patients; have been tested for competence in a competitive training environment; and, at least in training, have been the nonphysician provider primarily responsible for the care of very ill patients. Moreover, though such high-level nonphysician providers may not have taken the Hippocratic Oath, they share with physicians a professional commitment to the best interests of the patient. Lower-level nonphysician providers, like licensed practical nurses, medical assistants, and surgical

assistants, have also had formal training but are less highly trained. In addition, their roles in a medical interaction may be very limited, with them providing technical skills to the physician or high-level provider during the patient visit but not being responsible for the patient interaction as a whole. Finally, aestheticians are a different category altogether, as they are divorced from the medical model. Like high-level nonphysician providers, they may be primarily responsible for an entire patient interaction, but this interaction is based on a commercial rather than a medical model. For aestheticians, patient safety is not a moral professional imperative but rather important for protecting licensure and maintaining a successful practice.

The above hierarchy describes which providers are most technically qualified to provide laser services safely. However, a provider who is capable of delivering safe and effective care may be more or less motivated to do so. Beneficial outcomes are contingent on the capacity to do good, combined with the willingness to use this capacity. Although individuals can vary with regard to motivation and integrity, again we can make some generalizations regarding the alignment of incentives. In particular, physicians who have a specialty certification have the most to lose from unsafe laser practices because both their specialty certification and their state medical license may be jeopardized by negligent care. Transgressions that do not culminate in license, certification, or hospital privileges revocation can nonetheless raise malpractice rates and severely damage professional reputation. A referral practice of a subspecialist in a laser-relevant specialty is unlikely to flourish if referrers are concerned that their patients will be poorly treated and possibly harmed. Thus, a laser-trained physician in a relevant medical specialty is most incentivized to be a safe laser practitioner. A laser-trained physician in a nonrelevant medical specialty would be slightly less incentivized because their professional reputation in their specialty field, which was not laser intensive, would be less vulnerable to adverse outcomes among their laser patients. Next would be licensed physicians, who would have at risk their medical licenses but not any specialty certifications. Nonphysician providers are much less incentivized to be safe. Usually partly or completely sheltered by the malpractice coverage of their supervising physicians, such nonphysician providers are less differentiated and can more easily retrain in a different type of medical practice if they are unsuccessful at laser treatment. Although it is unlikely that a nonphysician provider would be willfully careless, their limited training and emphasis on following procedures reduces their capacity for exercising critical judgment in unusual clinical cases that may entail special safety risks. Indeed, such providers may see themselves as instruction implementers rather than fully responsible caregivers, and they may be incentivized to act in accordance with

physician-generated protocols. As such, nonphysician providers would be incentivized to provide safe laser care if closely supervised by a safety-conscious laser-trained physician but less able and willing to do so in the absence of such. To the extent that a practice has many high-level and low-level nonphysician providers per physician, each physician may be able to provide only limited oversight, which may be insufficient to ensure patient safety in cases where special considerations require special decision-making and judgments.

CONCLUSION

In summary, more highly trained physicians are most capable of being safe purveyors of clinical laser services, and they are also most incentivized to utilize this capacity. Nonphysician providers are least capable and incentivized.

The question of exactly how this should be operationalized is a legislative one. Different states have differing requirements regarding who may perform laser services, which in some states are restricted to physicians alone but in most states can be delegated to nurses. Similarly, states have differing requirements regarding how many high-level (i.e., physician's assistant and clinical nurse practitioner) nonphysician providers a given physician can supervise; this would determine the extent to which physicians could delegate laser care. There are also divergent requirements regarding whether the supervising physician needs to be on-site or not and the extent of the supervision.

Based on the above explication, the following restrictions should govern the personnel providing cutaneous laser care to patients:

- (a) Care should be delivered by laser-trained physicians, ideally those in laser-relevant specialties; such physicians should be required to document adequate didactic training and numbers of supervised cases, as required by the specialty board, during their residency or fellowship training. Those in nonrelevant specialties or those without specialty certification should be required to demonstrate substantial didactic training, hands-on experience, and competence in laser use before commencing a comprehensive practice with multiple laser and energy devices. Such training should not be brief and cursory but rather should entail at least 3 to 6 months of full-time training in laser use; if full-time training is not possible, part-time training should be spread over a longer time interval until a commensurate amount of training is completed. Until such training is completed, independent laser procedures should not be performed.
- (b) Nonphysician providers should be used to deliver laser care only under the following conditions: (1) they are

supervised by a laser-trained physician, as described above; (2) no more than two such providers are supervised at one time by a given laser-trained physician; (3) the supervising physician is on-site during at least 50% of the time that laser services are delivered by a nonphysician provider, and the remainder of the time the nonphysician provider is cross-covered by another on-site laser-trained physician or by a laser-trained physician available by phone and able to come in to see a patient problem if necessary; (4) whether high-level or low-level nonphysician providers are employed, they are mandated to undergo safety training, follow diagnosis and treatment protocols developed by the laser-trained physician, and are required to report unusual patient presentations and outcomes to the laser-trained physician for evaluation and resolution.

The independent or quasi-independent delivery of cutaneous laser treatment by nonphysicians constitutes nonphysician practice of medicine and should not be countenanced under any circumstances. The medical licensure system and specialty certification were specifically developed to ensure that patients receive medical care from experts who are highly incentivized to provide quality care. Less-qualified providers do not have the knowledge base, the clinical experience, the specialized training, and the commitment to patient safety that is necessary to protect patients. No reasonable person would accept brain surgery from an independently functioning nonphysician, and the same safeguards should be implemented for cutaneous laser surgery.

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