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WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

2005-06

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Assembly

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Committee on ... Public Health (AC-PH)

COMMITTEE NOTICES ...

- Committee Reports ... CR
- Executive Sessions ... ES
- Public Hearings ... PH
- Record of Comm. Proceedings ... RCP

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... Appt
- Clearinghouse Rules ... CRule
- Hearing Records ... bills and resolutions
(ab = Assembly Bill) (ar = Assembly Resolution) (ajr = Assembly Joint Resolution)
(sb = Senate Bill) (sr = Senate Resolution) (sfr = Senate Joint Resolution)
- Miscellaneous ... Misc

Testimony

Assembly Committee on Public Health
August 30, 2006
Madison, WI
Clearinghouse Rule 05-118

Robert T. Bohannon
Assistant Director, State Affairs
(202) 842-3555
rbohannon@aad.org

Mr. Chairman, members of the Committee, I want to thank you for the opportunity to be here today to speak about this important issue. My goal is to shed some light on the policies of the American Academy of Dermatology Association (AADA), and address some of the misconceptions and misinformation that have been put forth since the notice of CR05-118 was published. There are several physicians present today who will address the specific safety concerns regarding the proposed changes to this rule. I will address how the AADA developed our policy and why, as well as the allegations that proponents of this rule change have recently made public. Also, I will discuss some examples of statutes and regulations from other states that appropriately protect patient safety.

Specifically, the AADA has two policies regarding the practice of medicine (Position Statement on The Practice of Cutaneous Medicine) and the use of non-physicians personnel (Position Statement on The Use of Non-Physician Office Personnel). I have attached copies of both of these to this document.

For the past several years, the AADA has increasingly heard complaints from members about the growing number of patients being seen for complications from procedures performed by non-physicians. This includes burns from lasers, skin conditions that were treated with lasers that caused the condition to worsen, and improperly performed injections. Dermatologists were also concerned about physicians (some of which are their colleagues in dermatology) who were letting financial benefits override patient safety by "supervising" multiple satellite locations where non-physicians were providing skin care services.

The issue was addressed through various committees and task forces within the AADA. Last year at our Solutions Summit in Dallas, TX, three workgroups of AADA members were established to address this issue. Overwhelmingly, the response from these workgroups was that dermatologists need to be directly involved in the care of their patients, and should be on-site when delegated medical procedures were being performed. Furthermore, these workgroups felt that a dermatologist should see all new patients in a face-to-face manner. This is necessary in order to establish the patient's appropriateness for a procedure, as

well as to determine if there are any pre-existing skin conditions that be adversely affected by a treatment.

In addition to these three workgroups, the AADA's Practice of Medicine by Physicians and Non-Physicians Committee addressed this issue in 2005. Through several meetings, the committee decided that they wanted to strengthen the AADA's policy on the use of non-physician office personnel. Again, this was due to complications and adverse outcomes that the committee members had witnessed in their practices. This committee, like the previous workgroups, decided that it was in the best interest of patient safety for the physician to be on-site and immediately available at all times. The Practice of Medicine by Physicians and Non-Physicians Committee made their recommendations to the Board of Directors last summer. The Board of Directors then voted overwhelmingly to amend the AADA's policy to require the dermatologist to be on-site and immediately available.

The AADA is not the only organization who has addressed this issue. For example, please see the attached chart outlining state-by-state laser regulations. According to this chart, twenty-eight states either allow only a physician to use lasers or have medical boards or state statutes that consider laser usage the practice of medicine. This is not the greed motivated work of dermatologists or a small subset of physicians trying to corner the market on aesthetic skin care – it is nationwide concern over the growing proliferation of medical spas where medical procedures are being performed without adequate physician involvement.

It also bears mentioning that non-physician providers such as physician assistants, nurses, and aestheticians are indispensable to many dermatology practices. Many states have a shortage of dermatologists, and non-physician providers help them provide service to more patients. That being said, the relationship is a dependent one. Dermatologists assume ultimate responsibility for patient care, diagnosis, and treatment. Most states require physicians delegating procedures to non-physicians to establish written protocols for delegation, and most states also stipulate that the delegating physician is ultimately responsible for the procedure. This is also reflected in the malpractice insurance that physicians must carry. I feel it is necessary to state that these are not adversarial or competitive arrangements. The AADA's policy of having a physician on-site and immediately at all times protects the physician responsible for the patient, the patient themselves, as well as the non-physician performing the procedure.

Next, I feel that it is necessary to address two letters that were written to this committee in support of CR05-118. These letters have several inaccuracies and misconceptions, and I believe it is essential that the correct information is presented.

Ms. Ann M. Derenne, a licensed aesthetician employed with Skin Tight Aesthetic Services, LLC, sent a letter on August 5, 2006 attacking the AADA's position as greed motivated and self-serving. Ms. Derenne's letter states that this is a "last minute attempt to derail long overdue clarification on aesthetician's ability to earn income in their state-approved field of practice." Our attempt to prevent aestheticians from performing microdermabrasion, chemical peels, and laser hair removal without a physician on-site does not restrict their scope of practice. Many dermatologists (and other physicians) utilize aestheticians as part of their practice. We are not disputing the fact that trained and licensed aestheticians are qualified to perform these procedures – we simply believe that a physician should be involved in the process to evaluate the patient's appropriateness for the procedure, and to be available for consultation should any unforeseen problem arise. Having a physician 120 miles away is not supervision at all. In the event of an emergency, a physician would not be able to reach the patient in any less than two hours. In this same paragraph, Ms. Derenne states that "this is a protectionistic ploy undoubtedly funded by a subset of physicians seeking to harm other physician's ability to earn income." Again, our request does not restrict anyone who is licensed to from performing the services they are trained to do. I also do not understand how the desire to have a physician on-site harms other physician's ability to earn income. The AADA's concern has nothing to do with who can earn income by providing a service.

Ms. Derenne also attacks the AADA's Position Statements on The Practice of Cutaneous Medicine and the Use of Non-Physician Personnel as not being legal standards of care. This is true. The main mission of the American Academy of Dermatology is the continuation of dermatologic education. As such our organization does not establish legal standards that physicians must adhere to within their practice to maintain membership. We are not a licensing or regulation board. We do offer a multitude of educational courses through our Annual and ACADEMY meetings, and do offer guidelines for practice management. Ultimately, dermatologists are governed by their respective state licensing boards and the laws affecting the practice of medicine within their state. The policies approved by our Board of Directors are recommendations for members based on experience, existing state laws and regulations, and best practices.

Ms. Derenne goes on to say that Wisconsin's aestheticians are among the "most highly educated, trained, and board certified tested aesthetic practitioners." We find this statement a bit perplexing, as Wisconsin's Barbering and Cosmetology Act does not require any continuing education for aestheticians. On the other hand, the state of Wisconsin requires at least 30 hours of continuing medical education every two years for physicians to maintain their license to practice medicine. Continuing medical education allows a physician to be up-to-date on the latest advances and treatments in their field, and allows them to best serve their patients. While aestheticians must have training before they are licensed, and some aestheticians may participate in continuing education courses in Wisconsin, there are no mandates requiring such. This is problematic due to the

evolving nature of aesthetic skin care services, where new advances are continually being made.

Ms. Derenne also indicates that requiring a physician on-site “would be a cruel and inhumane cost to ask Wisconsinites to bear.” This short-sighted and emotional response attempts to obfuscate the truth. Words such as “cruel” and “inhumane” should not be used as an attack on an attempt to preserve patient safety. The bottom line is that physicians are medically trained experts prepared to handle adverse patient reactions and to best evaluate a patient’s needs. Dermatologists spend years in education and training in order to best diagnose skin conditions, recommend courses of treatment for their patients, and to handle adverse incidents.

I would now like to address some of the misinformation contained in a letter from Ms. Sasha Parker from the Association of Medical Esthetic Nurses (AMEN). Ms. Parker indicates that the American Academy of Dermatology has proposed legislation across the country to “prohibit and/or inhibit licensed practitioners from working in their trained areas of esthetic/cosmetic specialty by requiring on-site supervision” and that we have used our “powerful dollar to sway congressional decisions.” As a representative of the AADA’s State and Grassroots Affairs department, I can say that this is absolutely false. Furthermore, during my employment with the AADA, we have yet to spend any money lobbying legislators on this issue. We have provided information and insight on various issues relating to the practice of dermatology, but any attempt to spin this as a special interest issue where aesthetic providers are a target is completely baseless and insulting.

Ms. Parker also says there is no specialty called cutaneous medicine. While most often this is referred to as dermatology, the over 14,000 members of the American Academy of Dermatology Association would disagree with her assessment. Cutaneous medicine refers to the practice of diagnosing, treating, or correcting human conditions, ailments, diseases, injuries, or infirmities of the skin, hair, nails, and mucous membranes. Furthermore, a search for medical textbooks online will yield many volumes on cutaneous medicine, such as *Principles and Practices in Cutaneous Laser Surgery* and *Cutaneous Medicine: Cutaneous Manifestations of Systematic Disease*. Also, the *Journal of Cutaneous Medicine and Surgery* is an academic journal dedicated to research and clinical aspects of skin disease and skin biology.

Ms. Parker’s letter closes by saying that on-site supervision “serves to benefit a small subset of physicians and surgeons.” The AADA’s Position Statement on the Use of Non-Physician Personnel is actually more restrictive than lucrative for dermatologists. This policy was partly born out of the concern of dermatologists and other physicians serving as a “medical director” for multiple medical spas, where non-physicians were performing medical procedures without appropriate medical supervision. Additionally, the AADA, the Florida Medical Association,

and the Florida Society for Dermatology and Dermatologic Surgery supported legislation earlier this year (Florida HB 699) that restricted the number of aesthetic skin clinics a dermatologist could supervise where physician assistants and nurse practitioners were performing medical services. If our concerns were not about patient safety, we would not be supporting this type of legislation, and would encourage our members to seek lucrative offers as medical directors for medical spas. This bill was signed into law several months ago.

In closing, I would like to suggest at the very least that this issue be examined further before any decisions are made. CR05-118 indicates that a study was not performed to collect factual data when developing this rule. CR05-118 has the potential to adversely affect patients in Wisconsin. We believe that in order to best protect patient safety, a physician should be on-site and immediately available when medical procedures are performed by a non-physician. Wisconsin already addresses supervision requirements for physician assistants working under the supervision of a physician. We feel it is appropriate to further strengthen the supervision requirements for other non-physicians that are performing medical procedures. The American Academy of Dermatology Association and our members will be more than happy to work with this committee to help develop an appropriate rule.

Thank you for your time and consideration.



American Academy of Dermatology and AAD Association

Position Statement

on

The Practice of Cutaneous Medicine

(Approved by the Board of Directors February 22, 2002
Amended by the Board of Directors July 23, 2005)

The practice of cutaneous medicine includes, but is not limited to diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities of the skin, hair, nails and mucous membranes, by any means, methods, devices, or instruments.

The practice of cutaneous medicine includes, but is not limited to, performing any act or procedure that, by its intended or improper use, can alter or cause biologic change or damage living tissue. Living tissue is any layer below the dead cell layer (stratum corneum) of the epidermis. The epidermis, below the stratum corneum, and dermis are living tissue layers.

Such acts or procedures include, for example, the use of all lasers, light sources, microwave energy, electrical impulses, chemical application, particle sanding, the injection or insertion of foreign or natural substances, or soft tissue augmentation.

Because certain FDA-approved Class I and II devices, by their intended or improper use, can alter or cause biologic change or damage below the stratum corneum their use constitutes the practice of cutaneous medicine, which should be performed only by a physician or an appropriately trained person under the direct supervision of a physician.

This Position Statement is intended to offer physicians guidelines regarding the delegation of performance of medical procedures, but is not intended to establish a legal standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.



American Academy of Dermatology and AAD Association

Position Statement

on

The Use of Non-Physician Office Personnel

(Approved by the Board of Directors February 22, 2002;
Amended by the Board of Directors November 23, 2002;
Amended by the Board of Directors July 31, 2004;
Amended by the Board of Directors July 23, 2005)

The guiding principle for all dermatologists is to practice ethical medicine with the highest possible standards. Physicians should be properly trained in all procedures and services performed to ensure the highest level of patient care and safety. A physician should be fully qualified by residency training and preceptorship or appropriate course work. Training should include an extensive understanding of cutaneous medicine and surgery. It is the position of the AADA that only active and properly licensed doctors of medicine and osteopathy shall engage in the practice of medicine.

Under appropriate circumstances, a physician may delegate certain procedures and services to appropriately trained non-physician office personnel. Specifically, the physician must directly supervise the non-physician office personnel to protect the interests and welfare of each patient. Except in exceptional circumstances, 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 or service is being performed. It is the physician's obligation to ensure and document that, with respect to each procedure and service performed, the non-physician office personnel have received the proper training. All new patients and significant new problems in established patients should be seen by dermatologists in a face to face manner.

This Position Statement is intended to offer physicians guidelines regarding the delegation of performance of medical procedures and services, but is not intended to establish a legal standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
REGULATION BY STATE**

| STATE | LASER REGULATION | REQUIREMENTS RELATING TO SUPERVISION AND/OR DELEGATION OF MEDICAL FUNCTIONS TO UNLICENSED INDIVIDUALS | PENDING LEGISLATION/REGULATION |
|-------|--|--|---|
| AL | <p>The Board issued Declaratory Ruling No. 97-002 in June 1997 that states that use of laser hair removal devices in AL is the practice of medicine and such use shall be limited to physicians and those directly supervised by physicians, such that a physician is on the premises and would be directly involved in the laser treatment immediately if required.</p> <p>Board rules include the use of lasers in the definition of surgery.</p> | | |
| AK | | | |
| AZ-M | | <p>A.R.S. R4-16-301 through 303 provides for a Supervising physician to delegate specific Medical procedures to a medical assistant Consistent with the CAAHEP Standards for An Accredited Educational Program for the Medical Assistant.</p> | |
| AZ-O | | | |
| AR | | <p>Arkansas statute 17-105 to 111 governs the delegation of health care services to a physician assistant. Physician assistants may perform those duties and responsibilities, including the prescribing, ordering, and administering drugs and medical devices, that are delegated by their supervising physician. supervision shall be continuous, but does not require the physical presence of the supervising physician at the time and place that the services are rendered.</p> | |
| CA-M | <p>The Business and Professions Code includes the use of laser devices in the definition of the practice of medicine. Only physicians, dentists, physician assistants and nurses may use laser devices, including intense pulse light devices, with physician supervision within their legal scope of practice. The law requires written protocols and procedures relating to supervision. Laser hair removal may be performed only by a physician, or, when working with a physician, registered nurse or physician assistants.</p> | <p>The CA Business and Professions Code Relating medical assistants allows a medical assistant, under the supervision of a licensed physician, to administer medication by intradermal, subcutaneous, or intramuscular injections and to perform skin tests and other technical supportive services upon specific authorization. Authorized procedures must be within the scope of the physicians practice and</p> | <p>California SB 1423 Requires the Division of Licensing to establish standards for the continuing education of physicians and surgeons who perform laser procedures or supervise their performance.</p> |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
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|-------|--|---|--------------------------------|
| CA-O | <p>A 1997 Attorney General opinion states that physicians may not authorize medical assistants to perform laser treatments.</p> | <p>the physician must be physically present in the treatment facility during the performance of the procedures.</p> <p>California Business and Professional Code Section 2459.6 regulates the delegation of a task to an unlicensed person. Physicians may assign only those patient-related tasks that can be safely and effectively performed by an aide. The supervising physician shall be responsible at all times and shall provide continuous and immediate supervision. The physician shall be in the same facility as, and in proximity to the location where the aide is performing the task and shall be readily available at all times.</p> | |
| CO | <p>It is Board policy that the use of lasers for patient care constitutes the practice of medicine. The Board adopted a policy statement in November 1997 that lasers must be used by a Colorado licensed physician or under the direct and on-site supervision of a Colorado licensed physician. The Board expressed its intent that this be an employer/employee relationship such that the physician has direct control of the unlicensed person.</p> | <p>In November 2002, the Board held a hearing on proposed rules regarding the delegation of medical functions to unlicensed persons.</p> | |
| CT | <p>In December 1997, and confirmed in March 1998, the Board issued a Declaratory Ruling on Use of Lasers for Hair Removal. The Board ruled that a licensed physician with appropriate knowledge, experience and training should assess each patient prior to and during the course of hair removal treatment with laser therapy. Such physicians may delegate the operation of the laser for hair removal to a licensed physician assistant, registered nurse, or licensed practical nurse, who may render service under the supervision, control and responsibility of a licensed physician, provided the assessment of each patient is performed by the physician. The physician shall provide direct on-site supervision in the course of hair</p> | | |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
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| DE | removal with laser therapy. | In 1700 Board of Medical Practice, Section 21.1.1 states that a physician who delegates medical responsibility to a non-physician is responsible for that person's activities and must provide adequate supervision. No function may be delegated to a non-physician who is prohibited by statute or regulation from performing that function. Direct and indirect supervision are defined. Physicians who choose to have their patients followed by a non-physician must personally evaluate any patient at least every three months. | |
| DC | The Board of medicine considers the use of high-powered lasers (all Class IIIa, IIIb, and IV lasers as designated by the FDA) to be the practice of medicine. These may be used only by physicians, or by those exempt from the Medical Practice Act (such as nurses) while acting under the direct supervision of a physician. Florida also requires all high-powered laser systems to be registered with the Department of Health. Failure to do so may be grounds for disciplinary action against a physician and may result in a criminal penalty. Adm Rules 64B8-56.002 Statute Title 32, Chapter 501, Subsection 501.122 (Florida office surgery rules (64B8-9.009) include use of lasers in the definition of surgery) | | |
| FL - O | | | |
| GA | | | |
| GU | | | |
| HI | Only a physician may use a laser for hair removal. | | |
| ID | The Board adopted guidelines recommending physician evaluation and assessment of the patient prior to and following prescribed treatment with an intense pulsed light and/or laser | | |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
REGULATION BY STATE**

| STATE | LASER REGULATION | REQUIREMENTS RELATING TO SUPERVISION AND/OR DELEGATION OF MEDICAL FUNCTIONS TO UNLICENSED INDIVIDUALS | PENDING LEGISLATION/REGULATION |
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| IL | <p>device. If the actual treatment with an intense pulsed light device is delegated to a properly trained individual, the physician must maintain on-site supervision while treatment is being performed. The MPA creates an exemption from medical licensure only with regard to the use of Class I or II, nonprescriptive medical devices.</p> | | |
| IN | <p>State statute defines the use of lasers as surgery and, therefore, such use constitutes the practice of medicine. MPA. Article 4, Section 844 IAC 4-3-2 Surgical Operations</p> | <p>The MPA, Section 54.5, provides authority for physicians to delegate tasks or duties to licensed practical nurses, registered nurses, or other personnel.</p> <p>The MPA, IC 25-22.5-1-2 allows a physician to delegate a medical task that is within the physician's specific area of practice to an employee who is under the direction and supervision of the physician.</p> | |
| IA | | | |
| KS | <p>In April 2001 and amended in March 2002, the Board adopted regulations relating to supervision of light-based medical treatments. The regulations require physicians to have written practice protocol agreements with those who use a light-based medical device to provide a professional service under their supervision. Treatments are required to be performed at a location where the supervising physician maintains a practice or while the physician is physically immediately available. Treatments performed while the physician is not physically present are required to be performed within written operating parameters. Person receiving treatment are required to give consent. This rule does not apply to phototherapy in treatment of hyperbilirubinemia or to a chiropractor engaging in light-based physiotherapy. KSA Article 27, 100-27-1.</p> | <p>KSA 65-2872(g) establishes that persons performing medical services under the supervision of a physician are not unlawfully practicing medicine.</p> <p>KSA 65-28, 127 places specific duties on physicians who delegate, etc., acts that constitute the practice of medicine under the MPA.</p> | |
| KY | <p>Only a physician may use a laser for hair removal.</p> | | |
| LA | <p>Statute states that the use of lasers or chemical treatments for therapeutic or cosmetic purposes constitutes the practice of medicine. Only persons licensed under the laws of the state to</p> | | |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
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|-------|--|---|--------------------------------|
| ME-M | <p>practice medicine, veterinary medicine, dentistry, or podiatry shall perform laser surgery.</p> <p>In November 2001, the Board issued a position statement on the use of medical lasers for chemical skin treatments stating that such treatments are the practice of medicine and may be performed only by a licensed physician or by a non-physician who acts under the direct supervision of a physician licensed in L.A. Non-physicians who perform laser or chemical treatments in violation of the law, will be considered to be engaged in the unauthorized practice of medicine.</p> <p>Only a physician may use a laser for hair removal.</p> | <p>The MPA, Chapter 48, Section 3270-A states that nothing in this chapter shall be construed as prohibiting a physician or surgeon from delegating to his employees certain activities relating to medical care and treatment now being carried out by custom and usage when such activities are under the direct control of and in the personal presence of a physician or surgeon. The physician delegating such activities... shall be deemed legally liable for such activities of such persons, and such persons shall be in this relationship be construed as the physician's agent.</p> | |
| ME-O | | | |
| MD | <p>In October 2002, the Board issued a Declaratory Ruling (00-1) stating that the use of lasers for hair removal is a surgical act. Only physicians, certified nurse practitioners, registered nurses under Board of Nursing Declaratory Ruling (9701), and physician assistants may use lasers for hair removal.</p> | <p>Title 14 of the Maryland Code, 14-306, authorizes the BPQA to adopt rules and regulations relating to duties delegated by a licensed physician.</p> | |
| MA | <p>MA administrative code allows for use of laser acupuncture by acupuncturists.</p> | <p>The Code of MA Regulations, 243 CMR 2.00 allows a physician to permit a skilled professional or non-professional assistant to perform services in a manner consistent with accepted medical standards and appropriate to the assistant's skill.</p> | |

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|-------|--|---|---|
| MI-M | | Michigan Public Health Code, Article 15, part 161, 333.16215: <u>Delegation of acts, tasks, or functions to licensed or unlicensed individuals; supervision; rules; immunity</u> states that licensed physicians may delegate selected functions to licensed or unlicensed individuals when the functions are within the scope of practice for their profession and are performed under the physician's supervision. Functions that require physician expertise may not be delegated. | HB 5134 – Specifies that any procedure using a laser for dermatological purposes must be performed under the direct supervision of a licensed physician. Authorizes the Board to promulgate rules to prohibit or restrict the use of lasers. Signed by Governor 6-15-04 |
| MI-O | | | |
| MN | State statute defines the use of lasers as surgery and, therefore, such use constitutes the practice of medicine. | | |
| MS | In 1999, the Board adopted regulations stating that the use of laser devices for invasive or cosmetic procedures is considered the practice of medicine and is, therefore, limited to physicians and those directly supervised by a physician who is on the premises where the procedure is being performed. XIX Regulation Concerning Use of Laser Devices, Section 1 | | |
| MO | Only a physician may use a laser for hair removal. The Board appointed a subcommittee to review draft legislation in October 2000 . | | <u>Missouri HB 1328</u> Requires the state board of registration for the healing arts, in consultation with the state board of cosmetology and barber examiners, to promulgate rules that: (1) define the types and classifications of lasers and pulse light sources that are capable of coagulating tissue; and (2) require the direct supervision of a licensed physician for the use of such lasers and pulse light sources. |
| MT | Board rules include the use of lasers in the definition of surgery. | | |
| NE | The Board of Medicine and Surgery, however, has gone on record to state that use of a laser, for aesthetic procedures, or | The physician may not delegate the use of a laser to non-physicians, except that it may be | |

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| | any other procedures, is the practice of medicine and surgery. | delegated to a physician assistant with supervision and training consistent with the requirements for duties delegated to a physician assistant. | |
| NV-M | In December 1998 , the Board issued an advisory opinion indicating that the use of lasers is included in the definition of the practice of medicine. The opinion states that physicians are allowed to delegate certain responsibilities, including the use of lasers, only to employees qualified to perform procedures by way of special skills, education, or experience. | | |
| NV-O | | | |
| NH | State statute defines the use of lasers as surgery and, therefore, such use constitutes the practice of medicine. Only physicians and physician assistants who are licensed by the Board are allowed to perform laser procedures. | | |
| NJ | Board rules include the use of lasers in the definition of surgery. | | |
| NM-M | In 2000 , the Board revised rules and regulations on the use of lasers and light activated devices to incorporate board policy. The rule states that non-physician personnel performing hair removal on patients must have appropriate training in laser usage and the supervising physician must be on the immediate premises during the procedure. However, when the procedure is performed by a trained physician assistant, the supervising physician is not required to be physically present in the building where the surgery is being performed. In April 2002 , the Board adopted a rule stating requirements that must be met before unlicensed personnel may perform hair removal using lasers and light activated devices, including that the supervising physician must be on the immediate premises at all times during a procedure. | The MPA, Section 61-6-16(6)(3) states that the Act does not limit or prevent a physician from delegating any task or function to a qualified person otherwise permitted by state law or established by custom, except the dispensing of dangerous drugs. In November 2002 , the Board proposed new regulations relating to use of unlicensed personnel to perform procedures or operate equipment when not specifically licensed to do so. | |
| NM-O | | | |

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|-------|--|--|---|
| NY | <p>In August 2002, the NY State Board of Medicine passed a resolution recommending that the use of lasers and intense pulsed light for hair removal be considered the practice of medicine and thus be performed by a physician or under direct physician supervision.</p> | <p>Section 6530 of the New York Education Law defines professional misconduct and includes: 24) Practicing beyond the scope of practice permitted by state law and performing professional responsibilities a licensee knows he/she is not competent to perform..... 25) Delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified, by training, experience or by licensure to perform.</p> | <p>New York AB 634 Requires any person performing laser or intense pulse light devices hair removal to be a licensed physician or registered by the Department of Health as a laser or intense pulse light devices hair removal operator; makes violations a felony</p> <p><u>New York AB 4887 (SB 485)</u> States that licensed physicians, dentists, veterinarians, and podiatrists may use a laser or intense pulse laser device on human beings or animals within the scope of their professional practice.</p> |
| NC | <p>In July 1999, the North Carolina Board adopted a position statement that laser surgery is the practice of medicine and should be performed only by a physician or by a practitioner working within his/her scope of practice and with appropriate medical training under the supervision of a physician or other practitioner licensed to perform surgical services and preferably on-site. The statement was slightly amended in March 2002.</p> <p>In August 2002, the Board amended its position statement on laser hair removal to state that laser hair removal should be performed only by a physician or by an individual having adequate training and experience under the supervision of a physician who should be on-site or readily available to the person performing the procedure.</p> <p>In July 2005 the Board once again amended it's position statement on laser hair removal. It is the Board's position that each patient should be examined by a physician, physician assistant, or nurse practitioner prior to receiving the first laser</p> | <p>MPA, Chapter 90, Section 90-18, under practicing without a license, states that physicians are not prohibited from delegating any act or task to a qualified person which is otherwise permitted by law or established by custom.</p> <p>Rule 800 – adopted 11-15-02, establishes that 1) the responsibility for the delivery and outcome of any delegated function lies solely with the delegating physician, 2) adequacy and appropriateness of training for the function should be documented, 3) adequacy and appropriateness of supervision will be judged by the standard of care for a physician directly delivering the same medical service, and 4) delegated services cannot be re-delegated by anyone other than the responsible physician. In addition, prescribing of medication, other than refills, cannot be delegated under CO statute.</p> | |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
REGULATION BY STATE**

| STATE | LASER REGULATION | REQUIREMENTS RELATING TO SUPERVISION AND/OR DELEGATION OF MEDICAL FUNCTIONS TO UNLICENSED INDIVIDUALS | PENDING LEGISLATION/REGULATION |
|-------|--|---|--------------------------------|
| | hair removal treatment. The examination should include a full medical history and a focused physical examination. The position also defines "readily available" in terms of physician supervision. | | |
| ND | Only a physician may use a laser for hair removal. | Title 50 of the ND Adm. Code, Chapter 50-03-01-12 states that the code does not prohibit a physician from delegating any tasks or functions to a qualified person otherwise permitted by state law or established by custom. | |
| NMI | | | |
| OH | In 2000 , the Board adopted rules that state that the application of light-based medical devices to the human body is the practice of medicine, osteopathic medicine and podiatric medicine. Licensed physicians and osteopathic physicians may delegate the use of light-based medical devices approved by the FDA for phototherapy in treatment of hyperbilirubinemia in neonates to any appropriate person. Additionally, physicians may delegate the application of light-based medical devices to physician assistants and cosmetic therapists for the purpose of hair removal under certain conditions. Violation of the rules constitutes failure to conform to minimum standards of care. Ohio Adm. Rule 4731-18-01 through 04. | Ohio Adm. Rule 4731-23 regulates the delegation of medical tasks. Medical tasks may be delegated by a physician only under certain circumstances including that the person to whom the task is delegated is competent based on specific factors; the task is within the physician's expertise; and the supervising physician retains responsibility for the delegated task. | |
| OK-M | | | |
| OK-O | | | |
| OR | In January 2002 , the Board adopted a position statement that the medical use of lasers is the practice of medicine. Physicians using lasers should be trained appropriately and any physician who delegates a procedure using lasers or intense pulsed light devices to a non-physician should be qualified to do the procedure themselves. Allied health professionals employed to perform a laser or intense pulsed light procedure must have appropriate training and education and must be under the direct supervision of a licensed | | |

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|-------|--|---|--------------------------------|
| PA-M | <p>physician under written guidelines and/or policies. The ultimate responsibility for performing any procedure lies with the physician.</p> | <p>MPA, Section 17 allows a physician to delegate the performance of a medical act to a health care practitioner or technician if such delegation is consistent with the standards of acceptable medical practice; the delegation is not prohibited by board regulations; and/or the delegation is not prohibited by statutes or regulations relating to other health care practitioners.</p> | |
| PA-O | | | |
| PR | | | |
| RI | <p>12/15/2003 - Policy statement on office based esthetic procedures:</p> <p>It is the position of the Board that office based cosmetic or esthetic procedures that require the use of medical lasers, high-frequency radio waves, or injection of sclerosing chemicals or biologically active compounds [e.g. Botulinum toxin A, Botox] are medical procedures.</p> <p>Therefore, prior to undergoing such procedures patients must receive a medical evaluation for appropriateness by a licensed and qualified physician or other practitioner acting within his/her scope of practice.</p> <p>Although these procedures may be performed by an appropriately trained nonphysician working under the supervision and direction of a physician or other practitioner acting within his/her scope of practice, it is the supervising physician's [or other practitioner acting within his/her scope of practice] responsibility to assure that procedures are conducted appropriately; with appropriate assessment, consent and</p> | | |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
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|-------|---|---|--------------------------------|
| | <p>follow-up; and upon appropriate patients; and that all patient records are maintained according to standards applicable for medical records; and that patient privacy is protected. The supervising physician or other practitioner acting within his/her scope of practice is responsible for any procedures carried out by nonphysicians under his/her direction.</p> <p>Physicians [or other practitioner acting within his/her scope of practice] who perform and supervise such procedures must be able to demonstrate appropriate training and experience. Such training and experience may include, but is not limited to, residency or fellowship.</p> <p>The physician or other practitioner acting within his/her scope of practice is responsible to assure and document adequate training for individuals under his/her supervision.</p> <p>Additionally, other cosmetic procedures such as dermabrasion or the application of potentially scarring chemical treatments [e.g. so-called chemical peels] should also meet this same standard.</p> | | |
| SC | <p>In October 1999, the Board adopted a policy statement defining the use of laser devices as surgery and stating that laser surgery should be performed only by individuals licensed to practice medicine. Use of a laser device for hair removal may be performed by a licensed physician or may be a delegated medical act. If delegated, the person performing the procedure must be under the direct supervision of a physician who must be on-site when the procedure is performed.</p> | <p>The MPA, Title 40, Chapter 47, Section 40-47-60 states that the Act does not prohibit licensed physicians from delegating tasks to unlicensed personnel in their employment and on their premises if the task is routine in nature; is performed while the physician is present on the premises and readily available; the task does not involve the verbal transmission of a physician's order; and the unlicensed person is wearing a badge denoting their status.</p> | |
| SD | <p>State statute defines the use of lasers as surgery and, therefore, such use constitutes the practice of medicine.</p> | | |
| TN-M | <p>The definition of electrolysis includes the use of FDA</p> | | |

**USE OF LASERS/DELEGATION OF MEDICAL FUNCTIONS
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|-------|---|--|--------------------------------|
| | approved laser beam processes designated for permanent hair removal. | | |
| TN-O | | | |
| TX | <p>The Board considers the operation of lasers to be the practice of medicine and cannot be delegated to non-physician employees without the delegating/supervising physician being on site. The TX Dept. of Health is responsible for registration of persons who possess or use class IIIb and class IV lasers in the healing arts, veterinary medicine, etc. Rules state that individuals shall not use lasers on humans for medical purposes unless under the supervision of a licensed practitioner of the healing arts.</p> <p>In December 2001, Board proposed a draft rule on laser surgery.</p> | <p>The TX MPA in Section 3.06 states that a physician has the authority to delegate a medical act to qualified and properly trained persons if the physician determines that the act can be properly and safely performed by that person and such delegation does not violate any other statute. The delegating physician remains responsible for delegated medical acts.</p> <p>TX Board rules, Standing Delegation Orders Chapter 193.1-193.10 relate to delegation of Health care tasks to qualified non-physicians Providing services under physician supervision. A physician may delegate only health care acts that do not require the exercise of independent medical judgment and only when the physician is satisfied that the person has the ability and competence to perform the task. Effective March 6, 2003.</p> | |
| UT-M | | | |
| UT-O | | | |
| VT-M | | | |
| VT-O | | | |
| VA | | <p>Title 54.1 of the Code of Virginia provides that the code does not prohibit a licensed physician from delegating activities or functions to employees that are nondiscretionary and do not require professional judgment and are customarily delegated to such persons. The physician assumes responsibility for delegated tasks.</p> | |

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|-------|---|---|--------------------------------|
| VI | | | |
| WA-M | WA statutes include "laserpuncture" in the definition of acupuncture. | | |
| WA-O | | | |
| WV-M | | | |
| WV-O | | | |
| WI | | | |
| WY | | | |

Other Resources:

American Society for Laser Medicine and Surgery – *Standards of Care*, Adopted April 15, 1999



August 30, 2006

Dear Health Care Representative Hines, Freese, Underheim, McCormick, Grigsby, Benedict, Townsend, and Wasserman:

I am a Licensed Esthetician and a Licensed Esthetics Establishment owner, currently offering skin care services to include, but not limited to, microdermabrasion, chemical exfoliation and Intense Pulse Light treatments. I was introduced to these modalities in early 1999 as a manufacturer's representative for microdermabrasion equipment, and an educator and rep for clinical skin care products, including chemicals. Having spent 10 years prior in the salon and spa industry in Minneapolis, I quickly felt at ease with the speed and efficacy of these "lunchtime" treatments, and became eager to make a career in this quickly growing and lucrative industry. To my surprise, shortly after being recruited and moving to Wisconsin, I heard from a customer who had purchased a microdermabrasion device about 6 months earlier, that it had become illegal to estheticians. I had just started school for esthetics, investing in my future to be able to do non-invasive superficial treatments such as microdermabrasion and chemical exfoliations in a safe and appropriate manner. Just months earlier, as in many states, microdermabrasion was not regulated in Wisconsin. My colleagues found out the same way I did, through the grapevine. It is still unclear how quickly and quietly that became law without a public hearing. Needless to say, this very negatively affected my colleagues and me financially.

To make the best of a bad situation, I took as many microdermabrasion and chemical peel classes that I could find with the hopes of becoming an educator and go-to person. In addition, I began targeting physicians more aggressively to purchase the equipment. I was very surprised that the doctors who were interested were more often than not family practice physicians, hoping to offer cash services. Most physicians whom I contacted were not interested in microdermabrasion, indicating that it was trendy and superfluous. Now that this treatment is here to stay and potentially a lucrative cash service, it is suddenly "cutaneous medicine that if done improperly can cause permanent scarring and disfigurement". If this were truly the case, ONLY a physician should ever perform these services. Ironically, many of the doctors who purchased the equipment instructed me to train their office managers and wives, who would be doing the treatments.

Microdermabrasion equipment is considered a Class I Device as regulated by the FDA. Devices in this class are subject to the least amount of regulatory control, and they present minimal potential for harm to the user, according to the FDA. Other devices in this class include electric toothbrushes, bassinets, hair dryers, curling irons, surgical gloves, and hand held massagers. Intense Pulse Light devices, unlike lasers, are regulated as Class II devices, which are more complicated and present more risk than Class I devices. Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. Special controls may include special labeling requirements, mandatory performance standards and post market surveillance. Examples of Class II devices include powered wheelchairs, and

surgical drapes. In researching IPL devices on the FDA website, I found that all were listed as Class II.

In the 1980's, acids, specifically Glycolic in various strengths, were considered cutting edge products. At this time, consumers and professionals alike began calling practically every treatment that rejuvenated the skin a "peel. In reality, acid treatments performed in the salon/spa are actually forms of exfoliation. Esthetic level acid use is not to effect removal of the full epidermis or any of the dermis, i.e. it is not to "peel". Unfortunately, the term has become a misnomer in the esthetic industry, referring to chemical exfoliation, which is not a medical treatment. Chemical exfoliation, is considered very superficial and will exfoliate or reduce the stratum corneum, the layer of superficial dead skin cells, within an esthetician's scope of liability. It is the Cosmetic Ingredient Review Board's position that chemical exfoliations with Alpha Hydroxy acid strength of no higher than 30% and a ph of no less than 3 be used in a salon or spa setting. It is also their position that Beta Hydroxy acids be used in a strength no higher than 20 % with a ph of no less than 3. Treatments of this nature are very superficial and do not cause any peeling or "down time". Chemical exfoliation should remain in our scope of liability, without medical supervision. The change in nomenclature should be implemented immediately.

There is no doubt that IPL devices (Class II) and lasers, (Class III or IV) should have physician supervision. The most important component of any of these modalities is training. It is the position of the State Board of Cosmetology and Barbering, and of its legal counsel, after many years of research, debate, and a public hearing, that their licensees should operate these devices, with appropriate training, under the supervision of an off-site Wisconsin physician. I am in constant contact with my medical director, and work with him in his office several times a month, in addition to working in my own office. I am in favor of expediting CR 05-118. I have invested well over \$100,000 in equipment alone, and stand to lose it all if the rule is not implemented as is. Please feel free to contact me with questions or concerns at the following:

(608) 669-7546, aviderm@charter.net

Sincerely,

Avita Regan, Licensed Esthetician

Aviderm Clinical Skin Care



National Coalition of Estheticians,
Manufacturers/Distributors & Associations

MICRODERMABRASION PROCEDURES

It is the position of the NCEA that:

1. Microdermabrasion devices should be used by estheticians.
2. In addition to manufacturer supplied, device specific education, estheticians shall complete a course of study equivalent to that recommended by the NCEA.
3. If estheticians wish to use microdermabrasion devices they should take the necessary licensing education to include theoretical and practical application as part of their core curriculum or as continuing education modules.

*Disclaimer: The NCEA recommends that estheticians
abide by Federal, State and Local Regulations.*



*National Coalition of Estheticians,
Manufacturers/Distributors & Associations*

It is the position of the NCEA that:

1. Chemical exfoliation procedures should be performed by estheticians.
2. In addition to manufacturer supplied, product specific education, estheticians shall complete a course of study equivalent to that recommended by the NCEA.
3. If estheticians wish to perform chemical exfoliation procedures, they should take the necessary education to include theoretical and practical application as part of their core curriculum or as continuing education modules.

***Disclaimer:
The NCEA recommends that estheticians
abide by Federal, State and Local Regulations.***



August 30, 2006

To: The Committee on Public Health

Re: Testimony in Support of Clearinghouse Rule #05-118

Submitted by Laurel A. Thomas, Licensed Esthetician, Licensed Esthetic Instructor

Thank you for allowing my testimony.

The top layer of skin, the stratum corneum is a layer of dead skin cells. There are normally 15 to 30 layers of flattened and dead cells in the stratum corneum. Proper use of Microdermabrasion removes the first two layers.

The FDA labeled microdermabrasion as a Class I exempt device in 1998. Other class I devices include, curling irons, electric toothbrushes and scissors among others.

The rule, as it relates to the use of alpha hydroxy acid exfoliation preparations such as glycolic, is in accordance with the recommendation of the Cosmetic Ingredient Review Expert Panel of the FDA.

A trained esthetician can safely perform **MICRO**dermabrasion, a procedure we have been doing for eight to ten years prior to the rule review. We have not been able to find any complaints of injury or harm in the State of Wisconsin. Please do not confuse microdermabrasion with dermabrasion. Dermabrasion is done only by physicians, and is very different from microdermabrasion in procedure and results.

The dermatologists have defined the practice of cutaneous medicine as "performing any act or procedure that, by its intended or improper use can alter or cause biological change or damage living tissue. Living tissue is any layer beyond the dead cell layer," Given this definition, cutaneous medicine would include such procedures as: shaving, waxing, tattooing, electrolysis, nail services, ear and body piercing, sun tanning booths, acupuncture, massage, endermologie cellulite treatments, and more. All of these procedures are done without direct supervision of a physician. Many cosmetic lotions and creams stimulate regeneration of the cells and stimulation of collagen. These are over the counter products.

Estheticians are legally bound by the scope of practice of their licensure. If the rule were changed to require microdermabrasion, laser hair removal, and glycolic and salicylic acid treatments to be done only under the direct supervision of a physician, the physician's physical presence is in accordance with his or her discretion. This would mean that a licensed esthetician working in a physician's office could not perform these procedures if the physician were in surgery, or had a day off, and was not physically in the building. This has brought consideration by the estheticians to surrender their esthetic license so that they are not replaced by a layperson that could perform these procedures in a medical office where the physician's discretion does not have him physically present in the building. The state of Wisconsin could conceivably have non-licensed, non regulated individuals lacking in formal training of the skin, performing laser and high percentage levels of acid treatments.

Thank you for your consideration.



August 30, 2006

Senator Carol A. Roessler, Chairperson
Senate Committee on Health, Children,
Families, Aging and Long-Term Care
Room 8 South
State Capitol
P.O. Box 7882
Madison, WI 53707

Representative J. A. "Doc" Hines
Chairperson Assembly Committee on
Public Health
Room 10 West
State Capitol
P.O. Box 8952
Madison, WI 53708

Dear Senator Roessler and Representative Hines:

I am contacting you to comment on the proposed Clearinghouse rule 05-118. I apologize for contacting you so late on this, since the hearing is later this week. Although I thought that I was informed to a better degree than most doctors about legislative issues affecting patients and doctors (as a member of the WMS Council on Legislation), this matter was not really common knowledge. In fact, EVERY doctor I mentioned it too had not heard of the proposed change. Rather than apathy, I see that doctors and citizens need to hear more about this.

I share the concerns voiced by Wisconsin and national members of the AADA, ASDS, WSPS, WMS, and many physicians that these proposed rule changes could increase the risk of harm to Wisconsin citizens.

As a faculty member of UW School of Public Health and Medicine, I manage the clinical operations of our Dermatology Department. I work closely with other departments, such as Family Practice, Internal Medicine, Pediatrics, ENT, Oncology, Plastic and Reconstructive Care Surgeons, etc, to improve the coordination of care of the patient population that we serve. I also am very involved in oversight of physician extenders in UW Health system, by working with PA representatives, NP representatives, UWHC, and UWMF to coordinate the use of these valuable people in our health care system.

I am a board certified Dermatologist, focusing my clinical practice on skin cancer surgery (including reconstruction with skin grafts, etc.), laser surgery, and cosmetic cutaneous (skin) procedures such as chemical peels, microdermabrasion, dermabrasion, Intense Pulsed Light treatment, and a wide variety of laser procedures.

As part of my duties, I teach medical students, residents, and fellows in Dermatology and Dermosurgery technique, including the preoperative and postoperative management pertinent to each case.

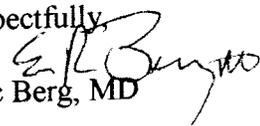
Our institution utilizes a wide variety of non MD support staff and extenders. With nurse managers, I oversee receptionists, Medical Assistants, LPNs, RNs, a PA, and a Nurse Practitioner. UWMF recently hired an esthetician, who works at the same site as her physician supervisors.

As a result of my broad and lengthy experience, I felt compelled to share my worries with people involved in the decision making in this proposed rule change. Here are the major areas of concern:

1. 120 miles is not a realistic distance to supervise from. My experience is that at UW Health, we are stricter than state rules in management of even more highly trained physician extenders, such as PAs and NPs. In most cases, we require on-site supervision, and review of records by the supervising MD. Placing an esthetician, who is not a medical professional, 120 miles from the supervising MD, would clearly result in less interaction/supervision. There exists an increased risk that procedures may not be properly done. Patients that shouldn't undertake procedures might have the procedure done, and risk having a skin cancer go untreated, acne under-treated, etc... Doctors will not be readily available to address complications, and we all know complications sometimes occur.
2. Liability. What happens when something goes wrong? How will patients and Doctors know that the medical chemical peel or microdermabrasion was done for the correct reason/diagnosis? Will malpractice carriers cover the risk of non MDs doing work 120 miles from the supervising MD?
3. This whole issue shows me that more discussions need to occur between the various licensing Boards, at least Medical and Barbering and Cosmetology, so this can be more fully explored. The input of more physicians, should give these boards, malpractice carriers, and the Governor's office a more balanced, comprehensive look at the issues at stake here.

I request that this proposed rule change not be adopted. Either table it for further discussion (as above), or rework it. I suggest that a group of all affected parties, including doctors, estheticians, licensing Board members, etc work together on this. For whatever reason, it appears the Committees and citizens of Wisconsin have not yet been fully informed on this matter. Direct supervision is in the policy statements of the AADA and ASDS. The WSPS recommends a 30 minute distance of supervision. Either of these is more reasonable than 120 miles. Will a patient drive to Milwaukee or Chicago to see the supervising MD, for preassessment, diagnosis, and treatment plan formulation, or travel happily that distance to evaluate a complication? I suggest that most doctors would not want to be placed in that situation.

Respectfully,


Eric Berg, MD

Vice Chair for Dermatology Clinic Operations
UW School of Public Health and Medicine
1 S Park Street
Madison, WI 53715





Wisconsin Medical Society

Your Doctor. Your Health.

TO: Members, Assembly Committee on Public Health
Rep. J.A. Hines, Chairperson

FROM: Mark Grapentine, JD – Senior Vice President, Government Relations
Jeremy Levin – Government Relations Specialist

DATE: August 30, 2006

RE: **Opposition** to CR 05-118 – Reducing Physician Supervision

On behalf of more than 11,000 members statewide, we appreciate this opportunity to share our concerns over Clearinghouse Rule 05-118, which will dramatically reduce needed physician supervision for certain medical procedures: microdermabrasion, chemical peels and laser hair removal/intense pulsed light procedures. Physicians most familiar with these procedures – dermatologists and plastic surgeons specifically – have not been able to register their strong concerns until today. Because their concerns center on patient safety for these often-complex procedures, we hope this committee will ask the Barbering and Cosmetology Examining Board to solicit advice from physician experts before implementing the rule.

There has been a flurry of activity on this rule in the past 90 days, which has raised many questions. The Committee may benefit from some basic clarifications.

A Business Professions Board – Not a Health Professions Board – Is Proposing the Rule Change

The Department of Regulation and Licensing is an umbrella agency providing administrative services to dozens of professions, dividing them between “business professions” and “health professions.” The Barbering and Cosmetology Examining Board is considered a business profession; in the Society’s opinion, rule changes affecting a patient’s health should originate from a health-related board, not a business board. Otherwise, situations happen exactly like the one before you today: non-health experts try to create a rule, but those best able to analyze those changes are unaware of the proposal until late in the proceedings.

This Committee finds itself stuck in the middle between well-intentioned supporters of the rule, and physicians concerned about increased potential for patient harm. The Administrative Rulemaking process usually takes care of this information-gathering; it has not done so with the rule before you today. Requesting that the Barbering and Cosmetology Examining Board renew its efforts to gather all the appropriate input can remedy this situation.

Physicians Support Current Regulations

Some supporters of the rule have accused various physician groups of trying to “take away rights” of those hoping to practice these procedures with little or no physician supervision. It is important to note that nothing can be taken away that is not already in existence. Existing regulations protect the patient by requiring physician supervision when appropriate for specific procedures. Physicians believe that current supervision requirements are necessary and should not be weakened.

Dermatologists/Plastic Surgeons Have Not Been Aware of the Rule Until 2006

Many letters submitted to the Committee talk about this rule being in the system for more than two years. Again, it bears noting that the Barbering and Cosmetology Examining Board is not a health-related board, and therefore understandably is not well-followed in the medical community. The Medical Examining Board (MEB) first heard of the rule in January, when it received a basic summary. There are currently no dermatologists or plastic surgeons on the MEB, again adding to the problem of gathering non-experts' opinions.

We understand why proponents are frustrated over what they consider to be a lengthy timeline for this effort. However, patient safety concerns are far more important than arbitrary timeline dates. Valid concerns remain, and therefore should be discussed.

Procedures in Question Not Black-and-White: Gray Areas Require Further Discovery

You have received a letter from the Wisconsin Society of Plastic Surgeons, signed by that group's vice president, Dr. Michelle Bonness. It is a well-written, easily understood summary of the concerns at issue. Dr. Bonness aptly describes the rules in surrounding states, the degrees of difficulty in all three of the procedures in question, and why further discussion is needed.

Her letter is also an example of the kind of input that is available once physicians are aware of issues pending in government that can affect patient care. We hope that in the future any group attempting changes to medically-related regulations works collaboratively with the state's physicians to accomplish what is surely the common goal: providing the safest, highest-quality care. In the meantime, the Committee can accomplish this goal by returning the rule to the Barbering and Cosmetology Examining Board.

Thank you for holding today's hearing and for listening to the Society's concerns. If you have any questions about this or any other issue, please feel free to get in touch with us. We can both be reached at 608.442.3800.



Re: CR05-118

As a resident of Wisconsin, practicing laser technician, senior clinical trainer for a laser/ light company, independent consultant in the medspa business, board member of the International Association for Aesthetic Physicians, member of International Medical Spa Association and a patient of non surgical procedures, I am requesting that the main consideration in the Practice of Cutaneous Medicine is education, protocols and benchmarking in this emerging new branch of medicine.

My thirteen years of hands-on clinical experience and training background of working with many different specialties and levels of expertise in training on laser/ light, microdermabrasion, Chemical peels and setting up protocols for the same, I have realized that the existing training protocols set by manufacturers and the industry is that doctors of every specialty, nurses, nurse practitioners, physicians, laser technicians, medical aestheticians are trained exactly the same. Regulation of aesthetic medicine should be focusing on training and education and not on any specialty since state regulations of lasers and pulsed-light typically do not differentiate among physician specialties, with the exception of Florida. The importance and emphasis should be on training and education rather than promoting a turf battle among specialties and interfering with existing lawful businesses. For example, Arizona has detailed educational requirements and refers people to approx 8 different schools and training programs across the state.

It's a shame to see this push to shut down hundreds of businesses which have been operating legally, with impeccable safety records, for fairly innocuous treatments like microdermabrasion and hair removal, particularly after the regulation had already gone through the appropriate channels and been approved in committee. Instead of hastily overregulating the industry, some states are putting together task forces like Massachusetts (newly signed bill by Gov. Romney) and as proposed in California (Senate Bill 1423.) These task forces have one year or so to study aesthetic spas to determine what problems and issues truly exist and suggest what should be done. These task forces typically include representatives from the Medical Board, Board of Nursing, Physician Assistant Committee, Board of Cosmetology, electrologists, and other experts in the field. As a group, they work together in structuring the needed education and training, whether it is continuing education courses, state or independent certification programs or the like.

As an independent contractor working with all levels of care givers and business in this cosmetic marketplace both in the state of Wisconsin and throughout the United States, I would very much like to sit on a panel to review these issues further.

I may be contacted at:

Cynthia Graf

6751 Locksley Lane

Cedarburg, WI 53012

262-707-5313



Representatives:

My name is Dr. Jason Rosenberg. I am assistant clinical professor of dermatology at The Medical College of Wisconsin, volunteer faculty at The Zablocki Veterans Administration Hospital, and in private practice in Milwaukee. I am a general dermatologist.

This rule, if it were to be enacted, would have no financial impact on my practice of cutaneous medicine. As documentation, I had my coding department pull the number of cosmetic visits since 1/1/06-8/29/06 where I have seen approximately 3500 patients. There were 13 visits during this time for cosmetic procedures. In comparison I had 11 visits for a rare type of autoimmune blistering disease called bullous pemphigoid.

I am concerned regarding this rule because it directly opposes the position statements of the American Academy of Dermatology, The American Society for Dermatologic Surgery, The American Society for Aesthetic Plastic Surgery, and The Wisconsin Society of Plastic Surgeons. Additionally the Wisconsin Rheumatology Association strongly disapproves of this rule.

On a personal level, this rule concerns me because of the patients that I have already seen who had adverse outcomes from the use of medical devices by non-medical personnel (estheticians) with inadequate supervision.

As background, it is important to note that intense pulse light is a multi modality device that not only are used for hair removal, but for blood vessel lesions, pigmented lesions (dark spots), wrinkles, scars, and acne.

The most egregious error I have seen was just 4-6 weeks ago at grand rounds at The Medical College of Wisconsin. A patient with lupus of the skin had laser therapy to a spot on her right lower extremity. The patient noted that the laser therapy was performed by a non-physician to decrease redness. This is inappropriate, and this inflamed plaque after treatment is now a permanent scar. The supervising physician for this laser clinic was not on site and is an anesthesiologist practicing well outside their scope of practice. This laser center is staffed by estheticians and supervised by a registered nurse. It should be noted that in the March 25, 2005 issue of the Jewish Chronicle a representative from this laser center stated that "(we) use real lasers, not 'intense pulse light lasers' which don't always produce the desired results and can cause bruising or scarring."

This same organization that staffs estheticians and registered nurses that perform "all services" stated that "the use of lasers for treatment of acne is 'just as effective as Accutane.'" This is misleading to the public, not supported in the medical literature, and has brought me many patients seeking help after non-physician performed, non-physician supervised treatment.

For example, last year a student from Marquette came to my office for severe, scarring acne. She stated that she had "laser" treatments for months from a non-medical professional without direct supervision. This did not clear her acne. I started her on Accutane, which is a high strength oral acne medication. At the end of the treatment course she completely cleared, but I do believe that the scarring would have been reduced if she was seen earlier.

I saw a Persian female with darkly pigmented skin treated with "laser" for acne by a non-medical professional at a cosmetic center without direct medical supervision. After thousands of dollars of treatment for her significantly inflamed acne she had no resolution, but had significant darkening of the skin from the treatment.

Other specialties are seeing these problems as well. Dr. Deborah Bernstein, an ophthalmologist, saw a young man this past spring who suffered from a corneal erosion (epithelium completely sloughs off the cornea) after a laser treatment for eczema. This was performed at a local spa. She noted in her letter that this laser treatment was not prescribed by a physician. She hoped that "with sufficient regulation, no one else will suffer from a painful and vision-threatening corneal erosion like this unfortunate patient."

Across the United States, state governments are tightening rules (not relaxing them) regarding lasers, intense pulsed light, microdermabrasion, and chemical peels. They are doing so to protect patients. In California "estheticians may not legally perform these treatments (laser and IPL) under any circumstances, nor may registered nurses or physician assistants perform them independently, without supervision."

The Louisiana State Board of Medical Examiners state that "only persons licensed under the laws of the state to practice medicine, veterinary medicine, dentistry, or podiatry shall perform laser surgery."

The Texas Board of Medical Examiners states that "the use of lasers/pulsed light devices for non-ablative procedures can not be delegated to non-physician delegates, other than an advanced health practitioner, without the delegating/supervising physician being onsite and immediately available."

We need to reach common ground with the respect to protecting patients and protecting the livelihood of estheticians. This rule, if it passes, although economically beneficial to plastic surgeons, dermatologists, other medical doctors, nurses, physician assistants, and estheticians, in my opinion does nothing but decrease protection for patients to adverse outcomes. This rule will, however, lead me to spending a greater proportion of my practice time trying to remedy unfortunate outcomes from under trained non-medical professionals performing medical procedures without adequate medical supervision.

X0700 AND X0720 BILLED YEAR TO DATE BY DR ROSENBERG

| <u>CODE BILLED</u> | <u>TIMES BILLED YTD</u> | |
|--------------------|-------------------------|-------------------|
| X0720.02 | 2 | } cosmetic codes. |
| X0720.03 | 4 | |
| X0720.04 | 2 | |
| X0720.06 | 2 | |
| laser [X0700.01 | 1 | |
| X0700.04 | 2 | |
| Total: | 13 | |

DR ROSENBERG'S USAGE OF 694.5 YEAR TO DATE

DX BILLED TIMES BILLED

694.5 11

Bullous Pemphigoid



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From: [redacted] wilson" [redacted] Add to Address Book Add Mobile Alert

To: mkederm@yahoo.com

Subject: AMEN policy statement

Date: Tue, 29 Aug 2006 21:42:41 -0500

- See your credit score: \$0
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Neal,

Thanks for forwarding the statement in support of AMEN , as written by the nurses who make up the organization and who wish to and certainly will benefit financially from the clarification of off site supervision.

The proliferation of medical "spas" has us all concerned. Specifically, the number of medical "spas" directed at the care of the skin are ever increasing. We are all concerned for the safety of our patients. It is an accurate observation to say that these medical skin spas are often under the medical direction of non-dermatologist physicians. We have to assume that part of the reason for this interest is purely financial. Keep this in mind. To say that the nurses who actually treat the clients (patients) on site have at least as good of training as the supervising physician may well be true, but this is hardly an endorsement of the practice. It may in fact be the crux of the problem This is because: a client (patient) first needs to have a diagnosis before the appropriate treatment is given. This is precisely where one could suggest that nurses are practicing medicine without a license.

Here is a brief example. I recently cared for a lovely retired RN who had an obvious recalcitrant dermatosis that I actually diagnosed after one visit. She had previously seen a dermatologist last fall and had a biopsy that was inconclusive, although she likely would have had the answer if she would have kept on seeing him. Instead she has a friend who ran a "laser spa" who offered to treat her "red spots" because they would most certainly "respond". They did not. They got worse, and scarred with hypopigmentation. Eventually an infectious disease MD sent her to me, and biopsies, blood work and common sense led me to a diagnosis of lupus. This is a potentially serious disease and one that warrants a specific diagnosis. Not only did she not get this at the laser center, but received treatment without knowing her diagnosis on more than one occasion. This was without suggesting that she see a dermatologist or that a DIAGNOSIS was important. My patient, who was not confrontational, was told by the RN that what she did was absolutely appropriate and that she knows more about lasers than most doctors. This might be true. But it is beside the point. She does not know more dermatology. Diagnosis is ,and always

will be the necessary precedent to appropriate treatment.
Thanks for listening,
Barbara D. Wilson, MD

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August 29, 2006

Dear Jason:

I am writing in support of your efforts to limit laser use to physicians and those under direct supervision of physicians. I want to relay a patient encounter that I had recently. Due to privacy laws, I will omit specific details.

This past spring, I saw a young man who suffered from a corneal erosion. This is when the epithelium completely sloughs off of the cornea. He woke up with sudden onset of pain, photophobia and diminished vision. On examination he was found to have a complete erosion of his corneal epithelium. He mentioned that the previous day he had undergone a laser for treatment of eczema at a local spa. This laser treatment was not prescribed by a physician. Without evidence to the contrary I believe that his corneal erosion was a consequence of improper laser use. I have seen other erosions such as this resulting from episodes of intense light exposure (i.e. tanning beds). Fortunately for this patient, after daily follow-up examinations and frequent eye drops, his cornea healed and his visual acuity improved, although will never return to the level prior to his laser "treatment".

I applaud and support your efforts to regulate the use of lasers for dermatologic diseases to those professionals trained in their proper medical application and use. I hope with sufficient regulation, no one else will suffer from a painful and vision-threatening corneal erosion like this unfortunate patient. I look forward to any feedback that you have regarding this issue.

Sincerely,

Debbie

Deborah W. Bernstein, M.D.
Medical Eye Associates, S.C.
1111 Delafield Ste 312
Waukesha, WI 53188
(262)547-3352

Ritz Laser leads clients to beauty and good health

By Erin Cohen

of The Chronicle staff

For someone looking to treat wrinkles or skin imperfections, spring "is the perfect time of year to get started," according to Kathy Buschmann, RN and CEO of Ritz Laser & Skin Care Center in Brookfield.

This is because there is no tanning allowed with laser treatment, and several treatments are necessary to achieve desired results, Buschmann said, so beginning now will ensure results by summer.

Buschmann offers a wide variety of laser services for hair removal, wrinkle reduction, and the treatment of scars, stretch marks, leg veins, as well as beauty services and advanced acne and enzymatic peels.

Buschmann, who opened Ritz in September 2002, "decided to open the center because there weren't many laser centers here," she said. "I felt it would be a service that this area would appreciate — a one-stop laser center for every-

thing."

Pam Gauger, of Waukesha, first went to Ritz to receive laser treatment for removal of underarm hair.

But she went on to get additional treatments for the "dark circles under my eyes" and also for some "redness across my nose and cheeks. I've had very good results."

According to Holly Bang, the sales consultant and marketing coordinator at Ritz, skin rejuvenation with lasers "can really deliver some radiance back to your skin. As women age, they lose that. This is something that every middle aged woman deals with."

She added that skin rejuvenation "exceeds women's expectations for what it can do for them, making them feel more confident about themselves."

The center features three treatment rooms, an 'after-treatment' room, where they offer makeup application. Ritz is popular for both men and women, said



Holly Bang and Kathy Buschmann

Buschmann because it doesn't resemble a "ladies spa." In addition, "I treat a lot of doctors and nurses," she said.

The center offers free initial consultations for all clients and conducts a "complete a complete medical history" for each client prior to treatment,

"to determine if laser treatment is appropriate," Buschmann said.

"We don't diagnose skin conditions," she added. "We treat them," with the assistance of Alberto A. Maya, M.D., who evaluates all treatment plans. Buschmann gained her

About the cover...

The Ritz Laser & Skin Care Center offers unmatched experience for worry-free laser treatment. Kathy Buschmann, RN, BA and owner of Ritz, is the person Candela Laser has trusted for over five years to train physicians and technicians in the use of their lasers. Ritz Laser & Skin Care Center is located just west of Ruby Isle in the Dix Building at 17585 W. North Avenue, Brookfield. 262-754-8800.

The article on the following pages is part of our paid cover opportunity. For more information, call The Chronicle at 414-390-5888.



Kathy Buschmann administers a laser treatment on a client.

background in laser treatments as a clinical nurse specialist for the Candela Laser Corporation, where she trained physicians, nurses, and their staff in the use of lasers. She only uses Candela lasers in her center today.

According to Bang, Ritz uses real lasers, not "intense pulse light lasers" which don't always produce desired results and can cause bruising or scarring.

In addition, Bang said, the use of lasers for treatment of acne is "just as effective as Accutane," an acne medication with many unwanted side effects, and much "more

natural."

Ritz is the only center in the state using all Candela lasers, the four of which are: the Candela Smooth-beam, used for skin renewal processes, including the treatment of acne scarring; the GentleLASE system, which is used for hair removal; the VBeam, which treats vascular lesions; and the GentleYAG, which is used for hair removal on dark skin tones.

'Multi-modality' approach

Buschmann says that the center uses a "multi-modality" approach to treating skin imperfections, and will even com-

Kathy Lenz

bine the use of different lasers "to achieve the results we want to get," as well microdermabrasion and chemical peels.

This approach, Buschmann said, is "softer and gentler" and results in "much greater success" in treatments.

Kathy Lenz, of Milwaukee, has been going to Ritz for treatments "since they opened."

"The first reason I went was because I wanted to get rid of facial hair," she said. Since then she has also had laser services to treat varicose veins, age spots, and has received microdermabrasion "to get rid of fine wrinkles."

"I've been very satisfied," she said. The staff members at Ritz "are very competent. They understand not only your desire to be attractive, but also the importance of being healthy and the need to do it safely. The services and the staff are very warm, caring and helpful."

Gauger agreed. The staff was "very accommodating and informative. Everything they did was very professional, and I will definitely go back."

All services at Ritz are administered by registered

nurses and licensed aestheticians who have received at least 50 hours of training,

Buschmann, who also continues to work as a laser trainer, and considers herself an expert in the field; someone who has "learned a topic and kept up with it. I've been doing this for six and a half years," she said.

Buschmann is constantly reading up on laser technology. "I think that's

important," she said, "having a good understanding of lasers, how they work and what they can do."

The center, which is located at 17585 W. North Ave., Suite 130, is open Monday, from 12-8 p.m. Tuesday and Thursday from 9 a.m.-7 p.m., Friday from 9 a.m.-4 p.m., and by appointment.

For more information or for a free consultation, call 262-754-8800, or visit www.ritzlaser.com.





My name is Heather Wells-Holtey and I am a board certified general dermatologist in Milwaukee, WI. As a physician, and specialist in cutaneous medicine, I am concerned regarding a few of the changes that have been made in the Clearinghouse rule 05-118.

My main concern relates to the level of supervision and the type of supervision for procedures clearly defined as medical by the rule, such as laser and intense pulse light. LASER and IPL procedures are performed using class IV medical devices that can cause significant damage including burning, scarring, retinal damage, and persistent pigmentary changes. These procedures require medical knowledge beyond the technical use of the equipment; it requires thorough understanding of the pathophysiology of skin and hair, as well as an understanding of the diagnosis involved and post-treatment management for an outcome with the least chance of complications.

Varying pigment types, underlying medical conditions (herpes labialis, atopic dermatitis, tendency for postinflammatory hyperpigmentation), and the potential side effects from laser treatments is well beyond the scope of practice for business professionals with a high school diploma and 3mo. of additional training. This limited medical education can place patients at risk of permanent damage to the skin (especially pigment alterations) during laser hair removal or use of an IPL device. For example, I have had several patients with darker ethnic skin types who have consulted with laser clinics that have recommended laser hair removal at a treatment parameter that would have likely caused significant pigmentary alterations had they not sought a second opinion from a dermatologist. I was then able to send the patients for laser hair removal to a clinic directly supervised by a dermatologist who was able to appropriately treat these ethnic skin types. I am not speaking of physician assistants, registered nurses, or advance nurse practice prescribers, but of estheticians who are by definition business professionals and not in the medical field.

With a supervisor 120 miles away from the place the treatment is being performed, no immediate assistance can be given. This would interfere with evaluation to determine the appropriate settings for the machines for special circumstances and medical conditions that would preclude the use of laser. Telephone

consultation is unacceptable in these types of situations because one would have to rely on a person's ability to describe what they are seeing, which is subjective and likely to be incorrect without the proper medical background.

Many of the lasers available today have multiple functions such as laser hair removal along with treatment of vascular lesions, treatment of pigmented lesions, and photorejuvenation. The laser companies market these many uses of the lasers to their buyers. I would be concerned that aestheticians would start using the lasers for treatment of vascular lesions and pigmented lesions. All of these other uses of the laser require physician diagnosis of the underlying condition before lasers can be used to treat the patient's concerns. It would be disastrous to have a melanoma lasered by an aesthetician.

In the rule regarding microdermabrasion, an aesthetician has to perform a pretreatment assessment on the client and the client has to give written consent. Based on the minimal baseline medical knowledge of aestheticians, the ability for them to determine if a procedure is safe for a patient is questionable. Additionally, aestheticians have no medical background to determine if people require prophylactic antiviral medications so as to prevent a herpetic (fever blister) outbreak after the microdermabrasion procedure. Even aesthetic grade microdermabrasion devices cause enough of a break in the epidermal barrier for the reactivation of the herpes virus and the potential spread to any areas where the skin barrier is compromised. This can lead to severe pain, suffering and scarring for the patient. This type of complication prevention requires consultation with a physician who can prescribe the appropriate preventative treatment so no permanent disfigurement arises. Also any procedure that requires obtaining consent supports the medical nature of a procedure and therefore constitutes the practice of medicine and should be adequately supervised by a physician.

All chemical peels cause disruption of the epidermal barrier. Therefore the risk of herpes viral reactivation and spread of staph or strep infections arising is very real and needs prompt medical intervention which cannot be done if a supervising physician or

licensed "non-physician" is 120 miles away. Can a bacterial or viral culture be performed by these non-medical business professionals to determine if a patient needs specialized medications?

Physicians and physician extenders such as PAs, RNP and RNs all require extensive medical training and continuing medical education requirements in order to practice in the state of Wisconsin and be licensed by the state of Wisconsin. Aestheticians in the state of Wisconsin do not. It concerns me that someone with little education and training can be put in a position to perform procedures that can have multiple complications.

Also there is nothing set up to require that aestheticians take courses for continuing their education. The field of laser procedures is growing and changing so quickly that all providers of these types of procedures must continue to educate themselves on the latest technologies and devices so as to provide the best care to the patients with the least amount of complications.

Physicians use aestheticians in their practice everyday and the relationship can be very rewarding for both parties. Physicians should be the ones evaluating a potential patient for a type of procedure so that the best procedure can be chosen and then tailored to the patient. Aestheticians can then perform the procedure under the direct supervision of a physician. Just as a physician prescribes a medication that is then filled by a pharmacist, an aesthetician can execute a procedure that has been prescribed by a physician.

My first priority as a physician is to "first do no harm". I feel that it is part of my Hippocratic oath to strongly oppose this clearinghouse rule 05-118 since unnecessary harm can come to unsuspecting patients when untrained nonmedical business professionals are blurring the boundaries and venturing into the practice of medicine.

Heather Wells-Holley, MD
2388 N. Lake Dr.
Milwaukee, WI 53211
414-291-1515



Thank you for giving me the opportunity to speak with you today. My name is Ann Derenne and I am a licensed esthetician.

I would first like to say that all of us who treat the skin put the client's safety first before any services are provided.

Estheticians are trained to work with the top layer of the skin - the epidermis. The type of machines and products used by estheticians are designed and formulated to work with this epidermis layer. Stronger machines and products are designed to penetrate below the epidermis layer and are only available if under the supervision of a physician. Training on both medical-grade and non-medical-grade machines is provided and required by the manufacturers/distributors of said machines. It should be noted that the training provided to both estheticians and physicians is almost always provided by an esthetician and that CR 05-118 already requires this advanced training.

The FDA has already approved microdermabrasion machines as Class I machines which do not require physician supervision as they are non-invasive. Dr. Bonness' letter of August 22, 2006 to the Committee for Public Health also refers to microdermabrasion as non-invasive. My clients like the fact that microdermabrasion services are non-invasive, and with several treatments, they can get the results they want. They like the fact that there is no downtime to heal and that they can go out in public right after microdermabrasion treatments.

We already have a rule in effect for chemical exfoliations. This rule allows estheticians to administer chemical exfoliation acid of 30% or lower and a pH of 3.0 or higher. Again, these limits were established as non-invasive standards. The sale of chemical exfoliation products outside of these acceptable ranges is restricted to physicians.

A considerable amount of work, time, and energy has already gone into CR 05-118. It would be a shame to throw the baby out with the bath water at this late stage just because there may be some need for further work as the field of esthetics evolves. CR 05-118 would give us all a good base from which to work.

Failure to implement CR 05-118, as written, would significantly harm my business and impose unnecessary hardships on my clients. My clients want me to be able to continue providing non-invasive skin care treatments and they are pleased with the results I can give them.

On behalf of myself, my clients, the hundreds of other estheticians in Wisconsin and their clients, I strongly urge you to pass CR 05-118 in its current form and without delay so that we may all continue to provide the non-invasive treatments we are trained to provide. Hundreds of estheticians' jobs, careers, and businesses are at stake here and I cannot possibly underscore the importance of immediately enacting CR 05-118 as written.



Jeannie M. Bush, Chairperson
Barbering and Cosmetology Examining Board
Bureau of Business and Design Professions
1400 East Washington Avenue
PO Box 8935
Madison WI 53708

Representative J.A. "Doc" Hines
Chairperson Assembly Committee
On Public Health
Room 10 West
State Capitol
P.O. Box 8952
Madison, Wisconsin 53708

September 10, 2006

In respect to CR05-118:

We appreciate the opportunity to follow-up to the public hearing that was held for CR05-118 on August 30th, 2006. We the members of The Greater Milwaukee Dermatology Society feel the following changes to the proposed rule should be implemented as per the committees call for compromise:

1. Esthetic grade microdermabrasion (as defined by industry standards) needs no supervision by a physician. *see education requirements.
2. Chemical exfoliation using alpha hydroxy acids of 20% or less and salicylic acids of 20% or less needs no supervision by a physician. *see education requirements and definition of chemical exfoliation.

Definition of chemical exfoliation: removal of stratum corneum (non-living tissue) only. The term chemical peel can not be used interchangeably for chemical exfoliation. This would be misleading to the public.

3. Medical grade microdermabrasion can be performed by an esthetician with direct (onsite) physician supervision.

Definition of direct (onsite) supervision: physician must be able to inspect the patient, direct the care of the patient, supervise treatment, and be immediately available to handle all potential adverse outcomes and complications.

4. NO chemical exfoliant greater than 20% alpha hydroxy acid or 20% salicylic acid will be performed by an esthetician regardless of supervision.
5. NO acne surgery (using lancets for the lateral piercing of whiteheads) can be performed by an esthetician.
6. Ear piercing is allowed without direct physician supervision.
7. NO cutting or paring of calluses can be performed by an esthetician.
8. The use of laser devices, intense pulsed light devices, and other light emitting devices by estheticians will be limited to the purposes of hair removal only. The use of these devices for the purposes of hair removal, will require direct, onsite supervision.

Education Requirement:

There needs to be a minimum level of education and training for the use of accepted procedures. These educational requirements need to be clearly defined. Additionally, this education needs to be independent of industry sponsored seminars and programs.

Quality Assurance:

The cosmetology and barbering board should have a committee that is responsible for maintaining standards in education and credentialing regarding accepted procedures.

Thank you very much for allowing us to have input on the changes to CR05-118. We would appreciate the opportunity to review changes to this rule after reviewed by the cosmetology and barbering board.

Sincerely,

Neal Bhatia, M.D.
Marguerite Compton, M.D.
Shiela Galbraith, M.D.
Manish Gharia, M.D.
Jack Maloney, M.D.
Jason Rosenberg, M.D.
Heather Wells, M.D.



Parrott, Douglas

From: Hoey, Joseph
Sent: Wednesday, September 13, 2006 4:39 PM
To: Wellnitz, Tim - DRL
Cc: Wichmann, Peggy; Martin, Larry - DRL; Sweet, Richard; Parrott, Douglas

Tim,

Representative Wasserman asked me to thank you and the Barbering and Cosmetology Board for your willingness to work with him on this issue. He has reviewed the most recent rule and appreciates the changes that the Board made. However, there are some things which he has some questions about. If possible, he would like to know the answers to the following questions:

1. Under current rules, licensees may provide client services constituting medical procedures only as directed, supervised and inspected by a physician who has the power to direct, decide and oversee the implementation of the client services provided in licensed establishments. BC 2.025(1). Sheldon would like to know if this level of oversight has ever been defined by the Board. Do current rules require onsite oversight? If not, what level of oversight is required?

2. The new rule adds a definition of "general supervision." The analysis that accompanied the rule states:

SECTION 5 adds a definition of general supervision to provide guidance to the licensee and the physician who wish to collaborate in the providing of certain services.

However, the only place the term "general supervision" appears in the new rule is in BC 2.025 (3).

BC 2.025 (3) Delegated medical procedures shall be undertaken only pursuant to formal written protocols setting forth the nature and scope of the procedures delegated, describing the supervisory plan, and indicating any contraindications to undertaking the procedure. A laser hair removal product or device, or intense pulsed light device shall not be used on a minor unless the minor is accompanied by a parent or guardian and only under the general supervision of a physician.

As written, the rule adds a requirement that whenever lasers or intense pulsed light devices are used on minors, the procedure must be under the "general supervision" of a physician. Nothing in the new rules removes the requirement that all laser hair removal procedures be provided under the more stringent "directed, supervised and inspected by a physician who has the power to direct, decide and oversee the implementation," standard in BC 2.025 (1). Did the Board think that this new definition of general supervision would supersede the standard under BC 2.025 (1) for all laser hair removal procedures?

3. The new rule refers to intense pulsed light devices only in relation to minors. No definition of an intense pulsed light device is provided in the rule. These devices can be used for procedures other than hair removal. Did the Board intend to allow these devices to be used on minors only, or for procedures other than hair removal? Do current rules allow licensees to use lasers for any procedures other than hair removal?

Please let me know if any of these questions require clarification. Thank you for your help.