Board adopts rules for using lasers

by Kenneth Aldridge, MD
Chairman, ad hoc Laser Committee
Vice chairman, Alabama Board of Medical Examiners

Recent years have seen rapid progress in the use of lasers for medical purposes and much of the use has moved from hospitals to office settings. With this increased use in non-credentialed settings, the Board of Medical Examiners (BME) has seen significant complications and problems as the result of laser treatments. Fortunately, most practitioners have had no or only minor problems. But, as in office-based surgery, the few severe problems require guidelines to minimize problems as much as possible.

With this background, the BME initiated a program to develop reasonable guidelines for the medical use of lasers outside of medical centers. The Board formed an ad hoc committee composed of physicians from multiple specialties, a certified registered nurse practitioner and a physician’s assistant, who had hands on experience with the use of lasers. The Board charged this committee with reviewing medical lasers that are in common use and developing a set of suggested guidelines to increase safety for patients undergoing laser treatment. Because there is continual innovation of lasers, the guidelines were to be general enough to incorporate, as far as can be seen currently, future developments so that revisions to the guidelines could be minimized.

When the ad hoc committee submitted its report to the Board, the entire BME reviewed the report and, after minor changes, published it for public review and comment. Comments were presented verbally at an open hearing and were also received in written form. The members of the Board studied and discussed each and every comment. Many of the comments resulted in changes that were incorporated in the guidelines.

The second edition of the rules was published and additional written comments were received. Each comment was reviewed and a response provided. On Aug. 15, the BME adopted Administrative Rule 540-X-11, Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue as a final rule.

These guidelines will affect the manner and methodology in which numerous physicians use lasers. While it may be disconcerting to have to change routines, if physicians understand the underlying reasons for these guidelines, most will embrace them. The Board intends for these rules to provide as much safety for patients as possible. Also, because the Alabama Code allows only physicians to practice medicine, the guidelines delineate what treatments constitute the practice of medicine and, for these treatments, how the physician must practice to ensure that he or she is in control of their administration.

A link to the complete set of guidelines may be found in the Newsletter Links section (continued on page 4).
Alabama BME Newsletter and Report

A Message from the Executive Director

Laser rules increase physician responsibilities

by Larry Dixon

The Alabama Board of Medical Examiners’ new rules concerning the use of lasers went into effect on Sept. 20, 2007. All Alabama physicians utilizing lasers in their medical practices need to be certain that they are familiar with these rules, which will be enforced by the State Board of Medical Examiners. Physicians must be compliant with all requirements of the rules by Aug. 15, 2008.

The Board is aware that some physicians are agreeing to become designated as the “Medical Director” for spas and similar facilities where non-licensed personnel are performing procedures with lasers. The new rules will require that these physicians who are medical directors fulfill the requirements of the rules concerning the delegation of laser use to CRNPs, PAs and others. Delegates are designated in the rules as either level 1 (CRNPs and PAs) or level 2 (others who meet the educational requirements stated in the rules). The degree of supervision/oversight required from the physician for a delegate depends upon whether the delegate is a level 1 delegate or a level 2 delegate.

Physicians are being reminded by the Board of Medical Examiners that, if a physician agrees to become a medical director for the purpose of allowing the use of lasers by non-physicians, the physician should be extremely familiar with the requirements of these new rules and should have a clear understanding of where and the extent to which the duties of medical director will be performed. The Board is aware of instances where a non-physician laser technician has an arrangement with a physician to work in a physician’s office with supervision; however, unbeknownst to the physician, the non-physician laser technician also performs procedures at another location where the physician is never present. The non-physician claims, in advertising, that the physician is the medical director for all laser use by the technician.

Such an arrangement can increase the physician’s liability in the courts and with the Board of Medical Examiners. As a licensed physician practicing in Alabama, the Board deems that it is your responsibility to be aware of what is required for the use of lasers.

Your Medical License

As a physician, your license to practice medicine in the State of Alabama is one of your most important assets. It allows you to apply what you learned during years of school and post-graduate training to earn a livelihood to support your family. Exercise care to protect this asset.
Medical license renewal guidelines for 2008


The renewal period ends Dec. 31, 2007. Renewals filed between that date and Jan. 31, 2008, will incur a late penalty of $100. If a renewal is not filed by the end of the “grace period” (by Jan. 31), the license becomes inactive, and any performance of medical practice by the physician named on the license is subject to discipline for practicing medicine without a current license. Medical license revocation for non-payment of fees is not a disciplinary action.

When submitting a license renewal, either on-line or by hard copy, it is very important that the physician carefully read the questions and review the answers for correctness. Errors on an application are subject to fines up to $10,000. A response that is not only inaccurate but attempts to deceive could result in revocation of the license.

Beginning Jan. 1, 2008, physicians in collaborative practices located in Alabama must have paid by Dec. 31, 2007, an annual registration fee of $100 for each collaborative agreement. [See Newsletter Links at www.abme.org for the applicable rules.] Physicians who are covering physicians for collaborative practices are not required to pay a fee. All physicians who have a collaborative agreement with a certified registered nurse practitioner (CRNP) or certified nurse midwife (CNM) will receive a registration form after Oct. 1 that should be completed and returned with the applicable fee no later than Dec. 31, 2007. If the fee is not paid by Dec. 31, 2007, the physician does not meet the qualifications necessary to participate in the collaborative practice and must cease participation in the collaborative practice until the registration form is submitted and the fee paid. There is no grace period for this fee. Physicians with a collaborative practice who have not paid the fee by Dec. 31 will receive notice that their collaborative practice is not approved. Upon completion of the registration form and payment of the fee, the collaborative practice will regain approval.

A physician may collaborate with more than one mid-level practitioner provided that the total collaboration time with all mid-level practitioners does not exceed 120 hours per week. The fee must be paid for each separate collaborative agreement.

Some examples of how this procedure works are:
• A solo practitioner is the supervising physician for one CRNP. The supervising physician is required to submit one annual registration form and one annual fee of $100.
• A solo practitioner is the supervising physician for three CRNPs. The supervising physician is required to submit three annual registration forms, one for each CRNP, and three annual registration fees for a total of $300.
• A three-physician group employs one CRNP. One physician must be listed as the supervising physician in the collaborative practice agreement. The supervising physician is responsible for submitting one annual registration form and paying one annual registration fee of $100.
• A group of three physicians employs three CRNPs. One physician is the supervising physician for all three. The supervising physician is responsible for submitting an annual registration form for each CRNP and three annual $100 registration fees, a total of $300 per year.
• A group of three physicians employs three CRNPs. Each physician is the supervising physician for one of the three CRNPs. Each of the three supervising physicians is responsible for one registration form and one fee of $100, annually.
• A physician employs two full-time CRNPs (40 hours each) and two part-time CRNPs (20 hours each).

The physician must submit an annual registration form for each of the four CRNPs and pay an annual registration fee for each CRNP that is employed, a total of $400.
• A CRNP has two different supervising physicians. Each supervising physician is responsible for submitting a separate annual registration form and paying the annual $100 fee.

Covering physicians are not responsible for the annual registration or the fee. A covering physician must register with the Board as a covering physician and notify the Board when covering responsibilities terminate.

Physicians with questions about a collaborative practice arrangement should contact Cheryl Thomas, RN, or Pat Enfinger, RN, Collaborative Practice Inspectors for the Alabama Board of Medical Examiners, at (334) 242-4116.

Any license not renewed by Jan. 31, 2008, is REVOKED (not a disciplinary action).

A renewal application should be carefully reviewed by the submitting physician. False answers may result in significant fines.
To whom do these rules apply?

The use of lasers/pulsed light devices, energy sources, chemicals or other modalities that affect living tissue for the purpose of treating a physical disease, disorder, deformity or injury constitutes the practice of medicine (Alabama Code §34-24-50) and, thus, must be performed directly by a licensed physician or under the supervision of a licensed physician by a delegate, as defined in the guidelines.

Paragraph 540-X-11-.01(3) lists various practitioner entities that are not covered under the rule as long as the laser/pulsed light device, energy source, chemical or other modality that affects living tissue is used exclusively for the practice of their recognized specialty, and as long as the use is not considered the practice of medicine by the Alabama Board of Medical Examiners. The excluded entities are dentistry, physical therapy, occupational therapy, chiropractic and optometry. “Body art” procedures are likewise excluded as these are regulated by the Alabama Department of Public Health. And, these rules do not apply to the use of laser/pulsed light device, energy source, chemical or other modality that affects living tissue that occurs in a hospital as defined by Alabama Code §22-21-20.

What is physician supervision?

Before a physician may delegate treatment to a level 1 or level 2 delegate, the delegating physician must:
• Ensure that the patient is adequately informed and, prior to treatment, has signed a consent form that explains reasonably foreseeable side effects and complications that may result from the non-ablative treatment;
• Formulate and/or approve a written protocol that meets the requirements of the guidelines and accepts responsibility for any patient-specific deviation from the protocol;
• Review and sign the written protocol at least annually and review and sign any patient specific deviations from the protocol;
• Receive a periodic status report on the patient, including complications or problems encountered;
• Personally attend to, evaluate, and treat complications that arise;
• Remain on-site for non-ablative treatments performed by level 2 delegates and be immediately available for consultation, assistance and direction;
• Evaluate the technical skills of the delegate(s) performing non-ablative treatment, with particular attention to proper operation of the devices in a safe and effective manner and to appropriate reporting of complications and untoward effects from the procedures; this evaluation must be performed at least quarterly and must be documented.

What is direct physician supervision?

The physician must be in the physical presence of the patient being treated and directly observing the use of the modality by a delegate. (This level of supervision is addressed in the present rules only with reference to the use of electrocautery.)

What is on-site supervision?

The supervising physician must be in the same building as the appropriate, properly trained delegate performing a procedure. All treatments and procedures must be performed under the licensed physician’s direction and immediate personal supervision. [The physician must be on-site supervision requires that the supervising physician be in the same building as the appropriate, properly trained delegate performing a procedure.

(continued on page 5)
physically present on the premises and immediately available at all times that the non-physician is on duty. The physician retains full responsibility to the patients and to the Board for the manner and results of all services rendered.

To whom may a physician delegate procedures?

There are two levels of non-physician delegates. A level 1 delegate is a mid-level practitioner (an advanced practice nurse or an assistant to a physician as defined in Alabama Code §34-24-290) who is authorized in a written job description or collaborative protocol to use a specific laser/pulsed light device, energy source, chemical or other modality for non-ablative procedures. This delegate must meet educational requirements that are stated in the rules.

A level 2 delegate is any person, other than a level 1 delegate, who has met the educational requirements that are stated in the rules. A level 2 delegate may not use laser/pulsed light devices to perform non-ablative procedures without the delegating/supervising physician being on-site and immediately available.

If the physician is on-site for supervision, the performance of non-ablative treatments may be delegated to a properly trained delegate, acting under written protocols. Prior to the initial treatment for non-ablative treatment the physician must examine the patient, develop a treatment plan, and sign the patient’s chart.

What is non-ablative treatment?

Non-ablative treatment includes any laser/pulsed light device, energy source, chemical or other modality that is not expected to remove, burn or vaporize tissue. This includes treatments for laser hair removal.

May a delegate use electrocautery to perform a procedure?

A level 1 or a level 2 delegate may use electrocautery only under direct physician supervision.

What should a treatment protocol include?

The protocol should begin by identifying the physician(s) authorized to use the specific device, and who is responsible for the delegation of the performance of the specified procedure.

It should include decision criteria and a plan that the delegate should follow. Criteria to screen patients for the specific non-ablative procedures, identification of devices, specific settings, and methods for device operation should be included.

The protocol should include a description of the appropriate care and follow-up for common complications, serious injury and other emergencies as the result of non-ablative treatments.

Finally, the protocol should outline the method to document decisions made and a plan for communication with the supervising physician concerning specific decisions made and the time frame in which the documentation shall be entered into the patient’s record or medical chart.

What are the educational requirements for physicians and delegates?

Paragraphs 540-X-11-.07 and -.08 list the educational requirements for each level. The rule requires these educational activities for anyone administering a laser/pulsed light device, energy source, chemical or other modality that affects living tissue. For persons who are currently using a laser/pulsed light device, energy source, chemical or other modality that affects living tissue in their practice and who can satisfy the educational requirements, documentation of previous training is adequate. Continuing medical education in this field is strongly encouraged for those who use it in their practice.

May a properly trained delegate perform procedures at a site distant from the physician’s office or clinic?

A level 2 delegate shall not use a laser/pulsed light device, energy source, chemical or other modality that affects living tissue at a remote site. A level 1 delegate may, with authorization by a written collaborative protocol or written job description, use laser/pulsed light devices for non-ablative procedures without the delegating/supervising physician being on-site and immediately available. However, the delegating/supervising physician must examine the patient, develop a treatment plan and sign the patient chart before the level 1 delegate performs the first non-ablative treatment of a planned regimen for a specific patient at a remote practice site. Subsequent non-ablative treatments that are a continuation of the treatment plan documented in the patient’s chart may be performed by the level 1 delegate at the remote site without examination of the patient by a physician before each treatment.

(continued on page 6)
Use of methadone for chronic pain management

by David P. Herrick, MD, and Bradley P. Katz, MD

EDITOR’S NOTE: Both Dr. Herrick and Dr. Katz are anesthesiologists and practice pain management in Montgomery.

Much maligned and frequently misunderstood, methadone manages to stay in the limelight for both the public and the physician. As recently as late August 2007, methadone garnered front-page coverage by The Birmingham News in an article detailing methadone’s role in addiction treatment and the controversies that continue to swirl around that topic. What is sometimes forgotten is that methadone has a legitimate role in the treatment of chronic pain.

Originally developed by the Germans in the late 1930s, methadone is a long acting synthetic opioid. Like other opioids, it has a strong, long acting affinity for mu receptors. Because it has a half-life of 24 to 36 hours or more it can be dosed as infrequently as once or twice per day.

Caution must be taken in initiating therapy, as with all opioids, because effects such as depressed respiration and sedation can occur and persist after the analgesic effects have subsided. As a rule, methadone has fewer sedating side effects than morphine but has a similar abuse potential. Because of this, care must be taken by the clinician to slowly titrate the drug to effect.

Used with care, methadone offers an excellent and very affordable option to manage chronic pain. Additionally, methadone is thought to be an NMDA receptor antagonist. This property gives it an additional potential benefit over other opioids in that it may more effectively treat neuropathic pain.

A common misconception among patients and physicians is that special licensing is required for prescribing methadone. For the treatment of chronic pain, a physician must have a DEA license and a state-issued controlled substances certificate. To use methadone for drug detoxification or addiction treatment requires specific federal certification in addition to licensure. This is an important distinction, and documentation in the medical record of the reason for treatment is essential.

As with all opioids, caution is necessary when prescribing methadone, whether it is given for pain relief or for detoxification. The Alabama Board of Medical Examiners has pain management guidelines to be followed. [See Newsletter Links at www.albme.org.]

Methadone, like all long acting opioids, should be used for chronic, not acute, pain syndromes, except for use in the addiction treatment realm.

Use of Lasers continued from page 5

What if a supervising physician is temporarily unable to supervise to the extent required by the rules?

A supervising physician can make arrangements for an alternate physician to cover the supervision. The alternate physician must have equivalent training in the performance of non-ablative treatments as the primary supervising physician and shall affirm in writing to the BME that he or she is familiar with the protocols or standing delegation orders used at the site, will be accountable for appropriately supervising care, and has equivalent training in non-ablative procedures.

How does the Board know if I use lasers in my office or clinic?

Every licensed physician practicing within the state of Alabama who uses a laser/pulsed light device in any facility other than one defined in the Code of Alabama as a “hospital,” which includes ambulatory surgical treatment facilities, must register with the Alabama Board of Medical Examiners with a form provided by the Board at the physician’s request.

After the initial registration, it is the obligation of the physician to notify the Board in writing of any change or addition of facility location or treatment modality where laser/pulsed light devices are used. Further, a physician registered to use a laser/pulsed light device, energy source, chemical or other modality that affects living tissue must notify the Board within three business days of an adverse event related to a procedure that resulted in hospitalization or a third degree dermal injury.

This is a summary of the Administrative Rule concerning laser/pulsed light devices, or other modalities that affect living tissue. Any physician engaged in this form of medical practice should carefully read and review the actual rule, which may be accessed through the Newsletter Links section of www.albme.org.
## Medical Licensure Commission

**July 2007**

- On July 25, based on the stipulation of the parties, the license to practice medicine in Alabama of **Kynard L. Adams, MD**, license number MD.10658, Montgomery, AL, was reprimanded, an administrative fine was assessed, and 24 hours of Category 1 continuing medical education are required before Dec. 31, 2007, due to failure to comply with continuing medical education requirements.

- On July 31, 2007, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Allan C. Walls, MD**, license number MD.17151, Columbia, SC.

## Board of Medical Examiners

**July 2007**

- None.

## Medical Licensure Commission

**August 2007**

- On Aug. 22, based on the stipulation of the parties, the license to practice medicine in Alabama of **Stephen D. Browne, MD**, license number MD.12788, Northport, AL, was reprimanded, an administrative fine was assessed, and 24 hours of Category 1 continuing medical education are required before Dec. 31, 2007, due to failure to comply with continuing medical education requirements.

- On Aug. 22, based on the stipulation of the parties, the license to practice medicine in Alabama of **Barbara L. Perrone, MD**, license number MD.21837, Montgomery, AL, was reprimanded, an administrative fine was assessed, and 24 hours of Category 1 continuing medical education are required before Dec. 31, 2007, due to failure to comply with continuing medical education requirements.

## Board of Medical Examiners

**August 2007**

- On Aug. 23, the Board entered an Order reinstating in full the Alabama Controlled Substances Certificate of **W. Ricardo Montiel, MD**, license number MD.18168, Prattville, AL. All other provisions in the June 28, 2005, Voluntary Restriction remain in effect.

## Medical Licensure Commission

**September 2007**

- On Sept. 5, upon the stipulation of the parties, the Commission entered a Consent Order assessing a fine against **Rajashaker P. Reddy, MD**, license number MD.26558, Atlanta, GA.

## Board of Medical Examiners

**September 2007**

- None.

### Notice regarding CME:

Physicians and PAs are required to maintain documentation of CME attendance and hours earned for a minimum of three years. More information can be obtained from the Newsletter Links section of the Board’s website, www.albme.org.
Look inside for important news from the Board of Medical Examiners that pertains to your license to practice medicine in Alabama.

Change of Address

The code of the state of Alabama requires that every licensed physician notify the Board of Medical Examiners in writing within 15 days of a change of the physician’s practice location address and/or mailing address.