



ALABAMA State Board of Medical Examiners Medical Licensure Commission

Newsletter and Report

www.albme.org

October – December 2012

Volume 27, Number 4

Inside:

Drug Diversion

Know the rules for proper prescribing.
– page 2

Prescription Forms

Use care to make prescriptions legible.
– page 3

Medicaid

Enrollment requirements effective Jan. 1.
– page 3

Collaboration

Mid-level practitioners require collaboration and quality assurance review.
– page 4

Ending agreements

Know the rules for terminating an agreement with a CRNP, CNM and PA.
– page 4

Special Section

Rules of the Alabama State Board of Medical Examiners
– pages i - viii

Complaints

Better communication may prevent some complaints.
– page 5

Continuing Education

CME calendar for 2013
– page 6

Public Actions

August – December 2012
– page 7

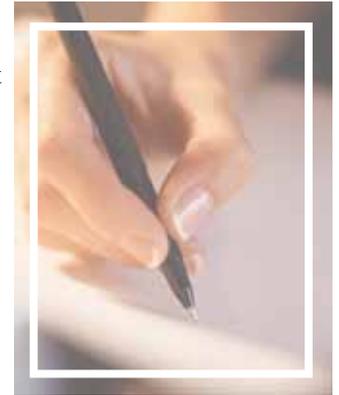
Health Department survey/email address request

Many of you who renewed your licenses online will have noticed a request from the State Health Officer to complete a Primary Care Physician Survey from the Alabama Department of Public Health. The Board and Commission appreciate those who accommodated the request and completed the survey. The Department of Public Health is required to provide the information to the Health Resources and Service Administration (HRSA) to evaluate primary care and mental health resources. The result of completing the survey may qualify your practice for Medicare incentive payments and other benefits.

You may have also noticed in the envelope containing your renewal receipts, another request for assistance. The Commission has asked that each physician provide a valid email address for the purpose of sending official license information from the Board and Commission and sending appropriate Health Alert Network messages as coordinated by the Department of Public Health. Most Health Alert Network messages will be generated by the Centers for Disease Control and Prevention or the Health Department's Epidemiology Division. This allows the sharing of urgent public health information about emerging situations. Before these messages are sent to physicians, they must be approved by the State Health Officer or Assistant State Health Officers. Your email address will not be subject to purchase or database requests.

If you have not filled out the Primary Care Physician Survey and wish to do so, please visit the link: <http://www.adph.org/Extranet/Forms/Form.asp?formID=3645>.

If you have not provided a valid email address to the Commission as requested, please visit the link: <http://www.albme.org/email.html>.



Update on chelation therapy study

In the last newsletter, the Board discussed its position on the use of chelating agents for various medical conditions. The Trial to Assess Chelation Therapy (TACT) was mentioned in the article. TACT is a study funded by the National Center for Complementary and Alternative Medicine and the National Heart, Lung and Blood Institute, that is the only ongoing blind, randomized clinical trial to determine the safety and effectiveness of EDTA chelation therapy in individuals with coronary artery disease. At the American Medical Association's November 2012 meeting, the authors presented a Chelation-Placebo Comparison, and while the authors reported a slight advantage for chelation over placebo in a combination of five separate endpoints (death, myocardial infarction, stroke, coronary revascularization, and hospitalization for angina), there was no advantage reported when considering the endpoints separately. The authors concluded that additional research is

See Chelation therapy, page 4

A Message from the Executive Director Board to address prescription drug diversion

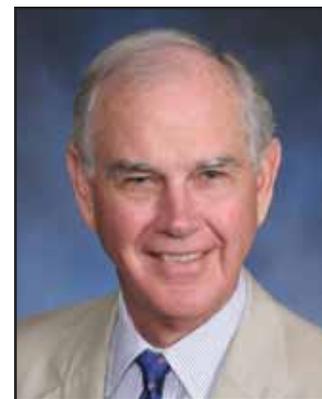
by Larry Dixon, Executive Director

Media sources have categorized the overdoses of diverted prescription opioids as more deadly than cocaine and heroin deaths combined. The Drug Enforcement Agency states prescription drug diversion is the number one drug problem in America. Hyperbole? Unfortunately not. There truly is a major problem in Alabama, as well as the rest of the nation, with prescription drug diversion, misuse and addiction. The increase in cases of diversion, misuse and overdose deaths is disturbing and has drawn the attention of public health officials and public policy makers. The Alabama Board of Medical Examiners is especially concerned with the diversion of controlled substances and is committed to raising awareness of the problem among physicians. The Governor has asked the Board and other agencies to participate in a local task force assembled to address prescription drug diversion issues and develop solutions. Governor Bentley is co-chair of the National Governors Association's Drug Diversion Task Force. It is expected that the work of these task forces will result in new legislation in 2013.

The Alabama Board of Medical Examiners is aware that most practitioners are quite conservative when prescribing controlled drugs; however, it is also cognizant that a small but significant number are overly aggressive and/or careless about their prescribing habits. Narcotics and pain drugs are not the only medicines diverted and misused. Other controlled substances such as benzodiazepines and amphetamines are often diverted and contribute to the prescription drug overdose problem.

The Board reminds physicians that it has rules in place that govern the use of controlled substances for the treatment of pain and the use of controlled substances for weight reduction. Additionally, the rules contain guidelines for prescriptions which physicians should follow. These rules have been printed on a special pull-out portion of this newsletter for easy reference. Keep in mind that rules are periodically amended. The most current versions are available at the Board's website, www.albme.org.

The Alabama Board of Medical Examiners is very seriously pursuing the inappropriate prescribing by physicians of all controlled substances and will strictly enforce its rules regarding prescribing in any setting. All physicians with the authority to prescribe controlled substances conferred by the state through their Alabama Controlled Substances Certificates should periodically review the above-mentioned rules, which are also available at the Board's website or upon request to the Board. Additionally, physicians who prescribe controlled substances should take advantage of the Alabama Prescription Drug Monitoring Program administered by the Alabama Department of Public Health. This program allows physicians to access the database of controlled substances prescribed to their patients. The Board does not recognize "I didn't know that" as an acceptable reason for inappropriate prescribing.



Larry Dixon



Alabama Board of Medical Examiners

George C. Smith Jr., MD
Chairman
Lineville

Richard M. Freeman, MD
Vice Chairman
Auburn

James G. Davis, MD
Birmingham

H. Joseph Falgout, MD
Tuscaloosa

Michael T. Flanagan, MD
Dothan

J. Daniel Gifford, MD
Decatur

William E. Goetter, MD
Fairhope

T. Michael Harrington, MD
Birmingham

B. Jerome Harrison, MD
Haleyville

David P. Herrick, MD
Montgomery

Juan Johnson, MD
Birmingham

John S. Meigs Jr., MD
Centreville

Paul M. Nagrodzki, MD
Birmingham

Timothy A. Stewart, MD
Huntsville

W. Jeff Terry, MD
Mobile

Larry Dixon
Executive Director

Patricia Shaner
General Counsel

Carla Kruger
Staff Editor
(334) 242-4116

Legibility of prescriptions, required information a concern to pharmacists

The Board receives numerous calls and complaints from pharmacists concerning illegible prescriptions and prescription forms that do not contain all of the required information. It is the practitioner's responsibility to ensure prescriptions are legible, it is clear who the prescriber is (by circling the prescriber's name on the form, for example), and all of the required information is contained on the prescription form.

The Board's prescription guidelines state the following:

- (1) All prescriptions for controlled substances shall meet the following requirements:
 - (a) The prescription shall be dated as of, and signed on, the day when issued;
 - (b) The prescription shall bear the full name and address of the patient to whom the drug is prescribed;
 - (c) The prescription shall bear the drug name, strength, dosage form, and quantity prescribed;
 - (d) The prescription shall bear directions for use of the drug;
 - (e) The prescription shall bear the name, address and Alabama Controlled Substances Certificate number of the physician prescribing the drug.
- (2) Where an oral order is not permitted, prescriptions for controlled substances shall be written with ink or indelible pencil or typewriter and shall be manually signed by the physician issuing the prescription. For purposes of this rule, "manually signed" requires a non-electronic, handwritten signature. Oral orders are not permitted for prescriptions for Schedule II and Schedule IIN controlled substances.
- (3) A prescription issued by a physician may be communicated to a pharmacist by an employee or agent of the physician.
- (4) A prescription may be prepared by an employee or agent of the physician for the signature of the prescribing physician; however, the prescribing physician is ultimately responsible for insuring that the prescription meets the requirements of this regulation.
- (5) When a physician prescribes a controlled substance, he or she shall not delegate the responsibility of determining the type, dosage form, frequency of application and number of refills of the drug prescribed.
- (6) Every written prescription for a controlled substance issued by a physician shall contain two signature lines. Under one signature line shall be printed clearly the words "dispense as written." Under the other signature line shall be printed clearly the words "product selection permitted." The prescribing physician shall communicate instructions to the pharmacist by entering his or her non-electronic, handwritten signature on the appropriate line.
- (7) It is improper for any prescription for a controlled substance to be signed by any person in the place of or on behalf of the prescribing physician.
- (8) It is improper, under any circumstances, for a physician to pre-sign blank prescription pads or forms and make them available to employees or support personnel.
- (9) It is improper for a physician to utilize blank prescription pads or forms upon which the signature of the physician has been mechanically or photostatically reproduced.
- (10) The Board may assess an administrative fine not to exceed \$10,000 for each separate violation or failure to comply with the prescription guidelines provided in this rule.

Medicaid announces enrollment requirements for providers who order, prescribe and refer

Effective Jan. 1, 2013, federal law requires that all physicians and other practitioners who prescribe or order services for Medicaid recipients, or who refer Medicaid recipients to other providers be enrolled as a Medicaid provider. As a result of this federal law, services rendered based on referral, order, or prescription will be reimbursable only if the ordering, prescribing, or referring (OPR) physician/practitioner is enrolled in the Alabama Medicaid Program. For more information on OPR and how to enroll as a provider in the Alabama Medicaid Program, please visit the Alabama Medicaid web site at www.medicaid.alabama.gov.

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.

Home assessments and home visits

The Board has concerns that many hospice organizations and other organizations that provide federally mandated home visits by mid-level practitioners are not adequately providing for the required 10 percent face-to-face collaboration time and 10 percent quality assurance review of charts in their practice models. All physicians in collaborative practices are subject to the requirement to be present with the CRNP at an approved practice site for not less than 10 percent of the CRNP's scheduled weekly hours as designated in the collaborative agreement. The collaboration time must be documented. Additionally,

collaborative practice physicians must review no less than 10 percent of the CRNPs records plus all adverse outcomes. The Board understands that these requirements are not a perfect "fit" for many of the hospice and home visit providers' practice models, but at present, there is no exception from the collaboration time and chart review requirements. Organizations appear to be meeting these requirements by holding weekly (or other appropriate

time period) Interdisciplinary Team (IDT) or Interdisciplinary Group (IDG) meetings where physicians and CRNPs are able to meet the collaborative time together requirement and at the same time meet the quality assurance review criteria by reviewing the assessments for the goals of hospice and home care.



Termination of collaborative practice/registration agreement

When a collaborative practice between a physician and a certified registered nurse practitioner (CRNP) or a certified nurse midwife (CNM) is terminated, the Board's rules governing collaborative practices require that the physician must notify the Board in writing the date on which the collaborative practice agreement was terminated. Notification is to be made within five business days after this date. Notification to the Board is easy. A letter can be submitted in writing, or the physician may use this simple Internet form: <http://www.albme.org/terminationform.html>. As this is specifically the responsibility of the physicians, physicians should ensure that this is done.

Likewise, when a registration agreement between a physician and a physician assistant (PA) is terminated, the PA and physician both must inform the Board in writing of the effective date of the termination of employment and the reasons for the termination.

Failure to notify the Board of termination of a collaborative practice or registration agreement may be considered by the Board as a violation of the rules for the purpose of approval of future applications for collaboration or registration.

On the Net:

Board Rules for Collaborative Practices:

<http://www.alabamaadministrativecode.state.al.us/docs/mexam/McWord540-X-8.pdf>

Board Rules for Physician Assistants:

<http://www.alabamaadministrativecode.state.al.us/docs/mexam/540-X-7.pdf>

Chelation therapy, cont.

needed to confirm or refute their results and explore possible mechanisms of therapy. They state, "TACT does not constitute evidence to recommend the clinical application of chelation therapy."

The Board reminds licensees that the only currently approved uses for EDTA are for severe heavy metal poisoning and hypercalcemia, and the Board strongly discourages its use outside those parameters.

On the Net:

"Board expresses concern regarding use of chelating agents." *BME Newsletter and Report*, Volume 27, Number 3: <http://www.albme.org/Documents/Newsletters/2012V27No3.pdf>

Slides from TACT presentation at Nov. 2012 AMA meeting: <http://www.slideshare.net/marilynmann/trial-to-assess-chelation-therapy-tact-slides>

540-X-4-.05 Controlled Substances Prescription Guidelines for Physicians

- (1) All prescriptions for controlled substances shall meet the following requirements:
 - (a) The prescription shall be dated as of, and signed on, the day when issued;
 - (b) The prescription shall bear the full name and address of the patient to whom the drug is prescribed;
 - (c) The prescription shall bear the drug name, strength, dosage form, and quantity prescribed;
 - (d) The prescription shall bear directions for use of the drug;
 - (e) The prescription shall bear the name, address and Alabama Controlled Substances Certificate number of the physician prescribing the drug.
- (2) Where an oral order is not permitted, prescriptions for controlled substances shall be written with ink or indelible pencil or typewriter and shall be manually signed by the physician issuing the prescription. For purposes of this rule, “manually signed” requires a non-electronic, handwritten signature. Oral orders are not permitted for prescriptions for Schedule II and Schedule IIN controlled substances.
- (3) A prescription issued by a physician may be communicated to a pharmacist by an employee or agent of the physician.
- (4) A prescription may be prepared by an employee or agent of the physician for the signature of the prescribing physician; however, the prescribing physician is ultimately responsible for insuring that the prescription meets the requirements of this regulation.
- (5) When a physician prescribes a controlled substance, he or she shall not delegate the responsibility of determining the type, dosage form, frequency of application and number of refills of the drug prescribed.
- (6) Every written prescription for a controlled substance issued by a physician shall contain two signature lines. Under one signature line shall be printed clearly the words “dispense as written.” Under the other signature line shall be printed clearly the words “product selection permitted.” The prescribing physician shall communicate instructions to the pharmacist by entering his or her non-electronic, handwritten signature on the appropriate line.
- (7) It is improper for any prescription for a controlled substance to be signed by any person in the place of or on behalf of the prescribing physician.
- (8) It is improper, under any circumstances, for a physician to pre-sign blank prescription pads or forms and make them available to employees or support personnel.
- (9) It is improper for a physician to utilize blank prescription pads or forms upon which the signature of the physician has been mechanically or photostatically reproduced.
- (10) The Board may assess an administrative fine not to exceed ten thousand dollars (\$10,000.00) for each separate violation or failure to comply with the prescription guidelines provided in this rule.

Upon an initial determination by the Board that any physician may have violated these rules and regulations the attorney for the Board shall serve upon the physician, either in person or by registered mail, an administrative complaint setting forth the specific violation or failure to comply, and shall advise the physician of his right to a hearing before the Board under the provisions of the Alabama Administrative Procedure Act §41-22-1 et. seq. *Code of Alabama*, 1975. The Administrative Complaint will further advise the physician that he may voluntarily execute and deliver to the Board a waiver of hearing and consent to the imposition of an administrative fine in an amount previously established by the Board. If the physician executes the voluntary waiver and consent then the Board shall be authorized to immediately assess the established administrative fine. If the physician declines to execute the voluntary waiver and consent or makes no response then the Board shall set a hearing to be held at least thirty (30) days after the Service of the Administrative Complaint. The hearing shall be considered a contested case and shall be conducted under the provisions of §41-22-12 *Code of Alabama*, 1975.

Rules of the Alabama State Board of Medical Examiners

All fines assessed by the Board shall be due and payable to the Board within thirty (30) days from the date the fine is levied or assessed unless a request for judicial review under Code of Ala. 1975, §§41-22-20, is filed, in which event the fine is due and payable to the Board thirty (30) days after the final disposition of the judicial review process. The name of any physician more than sixty (60) days delinquent in the payment of a fine which has been assessed by the Board which is not subject to judicial review shall be forwarded to the Medical Licensure Commission with a request that the annual certificate of registration of that physician not be renewed until the fine has been paid and satisfied in full.

All administrative fines received by the Board shall be deposited to the general revenues of the Board and may be expended for the general operation of the Board and for the development, administration and presentation of programs of continuing medical education for physicians licensed to practice medicine in Alabama.

Author: Wendell R. Morgan, Esq., and Patricia E. Shaner, Esq., Attorneys for the Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* 1975, §20-2-50, Act No. 86-451 (Reg. Session 1986), *Code of Alabama* 1975, as amended, §§34-24-380 and 34-24-382, as amended by Act No. 2002-140.

History: Adopted September 17, 1986. Filed September 19, 1986. Effective: October 27, 1986. Amended/Approved: June 6, 2002. Amended/Approved: July 17, 2002. Effective Date: October 24, 2002.

540-X-4-.07 Guidelines for the Use of Controlled Substances for the Treatment of Pain

(1) Preamble.

- (a) The Board recognizes that principles of quality medical practice dictate that the people of the State of Alabama have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.
- (b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.
- (c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute pain (Acute Pain Management Guideline Panel. *Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline*. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992) and cancer-related pain (Jacox A, Carr DB, Payne R, et al. *Management of Cancer Pain. Clinical Practice Guideline No. 9*. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994). The medical management of pain should be based on current knowledge and research and should include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.
- (d) The Board is obligated under the laws of the State of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug

Rules of the Alabama State Board of Medical Examiners

diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

- (e) Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.
 - (f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs – including any improvement in functioning – and recognizing that some types of pain cannot be completely relieved.
 - (g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.
- (2) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:
- (a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.
 - (b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
 - (c) Informed Consent and Agreement for Treatment. The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including
 1. urine/serum medication levels screening when requested;
 2. number and frequency of all prescription refills; and
 3. reasons for which drug therapy may be discontinued (i.e., violation of agreement).
 - (d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the

Rules of the Alabama State Board of Medical Examiners

appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

- (e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.
- (f) Medical Records. The physician should keep accurate and complete records to include
 1. the medical history and physical examination;
 2. diagnostic, therapeutic and laboratory results;
 3. evaluations and consultations;
 4. treatment objectives;
 5. discussion of risks and benefits;
 6. treatments;
 7. medications (including date, type, dosage and quantity prescribed);
 8. instructions and agreements; and
 9. periodic reviews.

Records should remain current, be maintained in an accessible manner, and be readily available for review.

- (g) Compliance With Controlled Substances Laws and Regulations. To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and must comply with applicable federal and state regulations. Physicians are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* and applicable state regulations for rules governing controlled substances.
- (3) Definitions. For the purposes of these guidelines, the following terms are defined as follows:
- (a) Acute Pain. Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.
 - (b) Addiction. Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as “drug dependence” and “psychological dependence.” Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.
 - (c) Analgesic Tolerance. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.
 - (d) Chronic Pain. A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.
 - (e) Pain. An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
 - (f) Physical Dependence. Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.
 - (g) Pseudoaddiction. Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.
 - (h) Substance Abuse. Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Rules of the Alabama State Board of Medical Examiners

- (i) Tolerance. Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Author: Wendell R. Morgan and Patricia E. Shaner, Attorneys for the Alabama Board of Medical Examiners.

Statutory Authority: *Code of Alabama* 1975, §34-24-53

History: Approved for Publication: December 21, 1994. Comment Period Ending: March 7, 1995. Approved/Adopted: March 15, 1995. Effective Date: April 21, 1995. Amended/Approved for Publication: September 14, 1999. Adopted: December 15, 1999. Effective Date: January 24, 2000.

540-X-17 Guidelines and Standards for the Utilization of Controlled Substances for Weight Reduction

Table of Contents

540-X-17-.01	Preamble
540-X-17-.02	Schedule II Controlled Substances
540-X-17-.03	Schedule III, IV and V Controlled Substances
540-X-17-.04	Initial Requirements
540-X-17-.05	Continued Use of a Controlled Substance for the Purpose of Weight Reduction
540-X-17-.06	Medical Records
540-X-17-.07	Conditions Warranting Discontinuance of a Controlled Substance

540-X-17-.01 Preamble.

- (1) The purpose of these rules is to provide guidelines, and in some instances standards, for licensed medical doctors (M.D.s) and doctors of osteopathy (D.O.s) who determine that the use of a controlled substance as an adjunct for a weight reduction regimen is medically appropriate for a patient.
- (2) The Board of Medical Examiners is obligated under the laws of the state of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including those used for the purpose of weight reduction, may lead to drug diversion and abuse by individuals who seek drugs for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.
- (3) Prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity should be based on accepted scientific knowledge and sound clinical grounds. All such prescribing and dispensing should be in compliance with applicable state and federal law.
- (4) Each case of prescribing or dispensing a controlled substance for weight reduction or the treatment of obesity will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines and standards, if good cause is shown for such deviation. Whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's individual needs will be considered by the Board in evaluating individual cases. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation.

Author: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* §§ 20-2-54, 34-24-53, 34-24-360

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012.

540-X-17-.02 Schedule II Controlled Substances.

A physician shall not order, prescribe, dispense, supply, administer or otherwise distribute any Schedule II amphetamine or Schedule II amphetamine-like anorectic drug, or Schedule II sympathomimetic amine drug or compound thereof or any salt, compound, isomer, derivative or preparation of the foregoing which is chemically equivalent thereto or other non-narcotic Schedule II stimulant drug, which drugs or compounds are classified under Schedule II of the Alabama Uniform Controlled Substances Act, to any person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.

Rules of the Alabama State Board of Medical Examiners

Author: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* §§ 20-2-54, 34-24-53, 34-24-360

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012.

540-X-17-.03 Schedule III, IV and V Controlled Substances.

- (1) Only a doctor of medicine or doctor of osteopathy licensed by the Medical Licensure Commission of Alabama may order, prescribe, dispense, supply, administer or otherwise distribute a controlled substance in Schedule III, IV or V to a person for the purpose of weight control, weight loss, weight reduction or treatment of obesity.
- (2) A written prescription or a written order for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity shall be signed by the prescribing physician on the date the medication is to be dispensed or the prescription is provided to the patient. If an electronic prescription is issued for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity, the prescribing physician must sign and authorize the transmission of the electronic controlled substance prescription in accordance with federal law and must comply with all applicable requirements for Electronic Prescriptions for Controlled Substances (See 21 CFR Parts 1300, 1304, 1306 and 1311, as amended effective June 1, 2010). Such prescriptions or orders shall not be called in to a pharmacy by the physician or an agent of the physician.
- (3) The prescribing/ordering physician shall be present at the facility when he or she prescribes, orders or dispenses a controlled substance for a patient for the purpose of weight reduction or treatment of obesity.

Author: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* § 34-24-53

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012.

540-X-17-.04 Initial Requirements.

- (1) Before initiating treatment for weight reduction or obesity utilizing any Schedule III, IV or V controlled substance, a physician should comply with the following:
 - (a) An initial evaluation of the patient should be conducted by and recorded by the prescribing physician prior to the prescribing, ordering, dispensing or administering of any drug. Such evaluation should include an appropriate physical and complete history; appropriate tests related to medical treatment for weight reduction; and appropriate medical referrals as indicated by the physical, history, and testing; all in accordance with general medical standards of care. Relative contraindications to the use of anorectic drugs should be addressed prior to prescribing or dispensing these medications.
 - (b) The patient should have a Body Mass Index (BMI) of 30 or above, or a BMI of greater than 25 with at least one comorbidity factor, or a measurable body fat content equal to or greater than 25% of total body weight for male patients or 30% of body weight for female patients, or an abdominal girth of at least 40 inches for male patients or an abdominal girth of at least 35 inches for female patients. BMI is calculated by use of the formula $BMI = \frac{kg}{m^2}$.
 - (c) The prescribing physician should assess and document the patient's freedom from signs of drug or alcohol abuse and the presence or absence of contraindications and adverse side effects.

Author: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* § 34-24-53

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012.

540-X-17-.05 Continued Use of a Controlled Substance for the Purpose of Weight Reduction or Treatment of Obesity.

- (1) A physician should not prescribe, order or dispense a controlled substance for the purpose of weight reduction or treatment of obesity in an amount greater than a thirty-five (35) day supply.
- (2) Within the first thirty-five (35) days following initiation of a controlled substance for the purpose of weight reduction or treatment of obesity, the patient should be seen by the prescribing physician, a physician assistant supervised by

Rules of the Alabama State Board of Medical Examiners

the prescribing physician, or a certified registered nurse practitioner collaborating with the prescribing physician, and a recording should be made of weight, blood pressure, pulse, and any other tests which may be necessary for monitoring potential adverse effects of drug therapy.

- (3) Continuation of the prescribing, ordering, dispensing or administering of a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should occur only if the patient has continued progress toward achieving or maintaining medically established goals and has no significant adverse effects from the medication.
- (4) A patient continued on a controlled substance for the purpose of weight reduction or treatment of obesity should undergo an in-person re-evaluation at least once every thirty-five (35) days. Once medically established goals have been met for an individual patient, it is strongly recommended that reduced dosing and drug holidays be implemented for those patients who need maintenance medication.
- (5) If the re-evaluation is delegated to a physician assistant or certified registered nurse practitioner, then the prescribing physician should personally review the resulting medical records prior to the continuance of the patient on a controlled substance for the purpose of weight reduction or treatment of obesity.

Authors: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* § 34-24-53

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012.

540-X-17-.06 Medical Records.

- (1) Every physician who prescribes, orders, dispenses or administers a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should maintain medical records in compliance with the provisions of this Chapter and Medical Licensure Commission Rule 545-X-4-.09, Minimum Standards for Medical Records.
- (2) The treatment of obesity should be based on evidence based medicine. (An example of evidence based medicine would include the Bariatric Practice Guidelines as established by the American Society of Bariatric Physicians and which can be found on the website www.ASBP.org.) The Board considers the promotion and use for weight reduction of controlled and non-controlled substances which have not been scientifically validated to be of questionable benefit (e.g., HCG, etc.). The promotion and use of these substances is under scrutiny by the Board for possible sanctions for non-legitimate medical use violations. Adequate medical documentation should be kept so that progress as well as the success or failure of any modality is easily ascertained.
- (3) At a minimum, every thirty-five (35) days when a controlled substance is being provided to a patient for the purpose of weight reduction or treatment of obesity, the physician or PA or CRNP should record in the patient record, information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

Author: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* § 34-24-53

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012. Amended/approved: February 18, 2012. Effective Date: June 18, 2012.

540-X-17-.07 Conditions Warranting Discontinuance of a Controlled Substance.

- (1) A physician should not initiate or should discontinue utilizing a controlled substance for the purpose of weight reduction or treatment of obesity of a patient immediately upon ascertaining or having reason to believe:
 - (a) That the patient has failed to progress toward medically established goals while under treatment with the controlled substance over a period of seventy (70) days, which determination should be made by assessing the patient with regard to previously established goals at least every thirty-five (35) days.
 - (b) That the patient has developed tolerance to the anorectic effects of the controlled substance being utilized.
 - (c) That the patient has a history of or shows a propensity for alcohol or drug abuse or has made any false or mis-

Rules of the Alabama State Board of Medical Examiners

leading statement to the physician or PA or CRNP relating to the patient's use of drugs or alcohol.

- (d) That the patient has consumed or disposed of a controlled substance other than in compliance with the treating physician's directions.
- (e) That the patient has repeatedly failed to comply with the physician's treatment recommendations.
- (f) That the patient is pregnant.

Author: Alabama Board of Medical Examiners

Statutory Authority: *Code of Alabama* § 34-24-53

History: Approved for publication: October 19, 2011. Effective Date: January 20, 2012.

Avoid complaints to the Board

The following is a reprint of a Newsletter and Report article from Jan. 2009.

“Can my doctor fire me for asking too many questions?”

“I want to file a complaint against my doctor; his office manager treats me like dirt and won’t let me talk to the doctor.”

“My son’s doctor told him to be quiet and learn to behave like a human being! I want his license pulled!”

This is a very small sampling of the types of calls the Board office receives every day. In an average week, we receive at least 50 complaints, 90 percent of which could have been avoided with a little more patience, professionalism or awareness of the patient’s educational or physical limitations.

By far, the most common complaint is rudeness on the part of the physician and/or the physician’s staff. Often this is not the result of any real discourtesy to the patient but a perception on the part of the patient of being rushed, talked down to, intimidated, bullied or misunderstood. Sometimes the patient or family member does not have adequate skills to cope with these feelings, and as a result they may become angry or hostile. When this happens, they often incur the frustration and anger of the physician or staff members in the office. It is up to the physician and staff to recognize and defuse this kind of situation before it becomes a problem. There are many learning opportunities available for physicians and their employees to gain experience and communication skills that can be useful in daily practice and called upon in the case of a problem patient.

The second most frequent type of call is more avoidable and less explainable than complaints of rudeness. In this case, the complaints come from pharmacists who experience difficulty making direct contact with a physician, or someone in authority, when

there is a question about a prescription. The pharmacist may have a question about the dosage strength or drug interactions, or may have important information about the patient receiving medications from other physicians. At times, the pharmacist is simply trying to ensure that the prescription is not a forgery or an attempt at forgery. In these cases, the pharmacist must be able to contact the physician in a timely manner. Most often the problem arises when a member of the physician’s staff fails, or refuses, to notify the physician of the pharmacist’s needs. The impact this problem has on patient care is serious and should not be minimized. Make certain that you have an acceptable procedure in place in to comply with these needs and deal with such problems.

We have seen many cases where there was not such a procedure and a staff member has authorized controlled substance prescriptions, or phoned in controlled substance prescriptions, without the physician’s approval. Unfortunately, some of the most trusted members of an office staff have obtained controlled substances for personal use, or for their family members, by phoning in prescriptions without the physician’s knowledge, authority, or approval. When this occurs, the physician should report the incidents to a local law enforcement agency or an area Drug Task Force. Such activity constitutes a Class C felony offense in Alabama and may be punishable by imprisonment and/or significant fines.

Less often, but still too frequently, we receive complaints that a physician’s office repeatedly failed to call a patient back about medications, health questions, test results, etc. Evidence suggests that these are often the same medical offices that pharmacists have experienced communication problems with. Again, the need here is to develop appropriate lines of communication

and procedures for taking and returning messages. It is an important part of your practice and may go a long way in helping to avoid complaints being made to our agency.

Complaints about medical records copying and transfer are very common. These issues range from patients having difficulty locating a previous provider to obtain records, to difficulties having copies of medical information transferred to a new provider. In some instances, medical offices have refused to transfer medical information or have failed to do so in a timely manner. This can interfere in the continuity of care, which could become a viable medical complaint. When a physician leaves a practice, patients should be notified in writing about the departure, as well as the procedure for transfer of their medical information. Also, the Medical Licensure Commission must be notified of any change of address within 15 days. If you receive a request to transfer records to another physician, it is customary to waive copying charges. Requests should be honored in a timely manner. If a patient requests a copy of his or her medical record, you may charge a reasonable fee (see “On the Net” below) and request payment in advance, but you may not withhold medical information because of an unpaid bill for medical services. This is another area where staff persons may be short circuiting communication between patient, staff and physician. You should be aware of the procedures in your office concerning medical records transfer/copying, and whether the procedure is operating efficiently.

Another area of confusion for patients is when medical services have to be discontinued. As previously mentioned, upon a physician leaving a practice, patients should be notified in advance and when possible, in writing. *see Avoiding complaints, page 6*

2013 CME Calendar

March 2-3

Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls, Montgomery

April 11

Ensuring Quality in a Collaborative Practice, Mobile

April 12-14

MASA Annual Session: Patient Care Beyond Your Office Door, Mobile

August 9-11

Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls, Perdido Beach

September 20-21

MASA Technology Symposium, Montgomery

November 22

Medical Ethics, Birmingham

November 23-24

Prescribing and Pharmacology of Controlled Drugs: Critical Issues and Common Pitfalls, Birmingham

December 5

Ensuring Quality in a Collaborative Practice, Birmingham

Visit www.masalink.org for more information.

www.albme.org

The following forms are available on the BME's Website:

- Retired Senior Volunteer license application
- Request for waiver from CME due to retirement
- Address change form
- Application for replacement of lost or destroyed license
- Malpractice payment report form for insurance companies
- Dispensing physician registration form
- Office based surgery registration form
- Office based surgery adverse event reporting form
- Laser/pulsed light device procedures registration form
- Laser/pulsed light device procedure adverse event reporting form

Avoiding complaints, cont.

If the practice is closing, the patients should be provided with as much advance notice as possible in order for them to secure another practitioner and have medical information transferred. It is when patients receive no notification, or cannot contact the physician to request medical information, that they call the medical board to complain. This can give the appearance of patient abandonment. Sometimes a patient will have to be "fired" for one reason or another – suspected drug diversion, non-compliance, unpaid bills, etc. You can discharge a patient for any reason or no reason at all, but you cannot do so without adequate written notice and provisional coverage while the patient is finding another physician. The provisional coverage does involve providing adequate parting medications. You cannot refuse to treat a non-discharged patient due to unpaid bills.

Our agency's staff often attempts to resolve these issues by providing the individual with pertinent information or by contacting the physician for more information. The physician's timely and full cooperation with Board staff in providing the requested information is important. If we can satisfy the complainant at this stage, a formal complaint and a visit from a Board investigator might be avoided.

Public Actions, cont.

BME – November 2012

◆ On Nov. 14, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of **Allan C. Walls, MD**, license number MD.17151, Birmingham, AL.

MLC – December 2012

◆ On Dec. 10, the Commission entered an Order placing on probation the license to practice medicine in Alabama of **Mary Dell Railey, MD**, license number MD.25741, Birmingham, AL.

◆ On Dec. 31, the Commission entered an Order denying the application for reinstatement of license of **Steven J. Dick, MD**, license no. MD.21416, Decatur, AL.

BME – December 2012

◆ On Dec. 12, the Board accepted the voluntary surrender of the certificate of qualification and license to practice medicine in Alabama of **James R. Frede, MD**, license number MD.30367, Kahului, HI.

Actions taken regarding failure to comply with CME requirements

Joint Petition, Stipulation and Consent Orders dated Aug. 22:

- **Vaughn H. Mancha, Jr., MD**, MD.14167, Montgomery AL
- **Danny Trammel Hood, MD**, MD.7855, Greenville, AL
- **Richard A. Stehl, MD**, MD.27593, Montgomery, AL

Joint Petition, Stipulation and Consent Order dated Oct. 24

- **Larry Jan Davis, MD**, MD.4217, Huntsville, AL

Report of Public Actions of the Medical Licensure Commission and Board of Medical Examiners

MLC – August 2012

◆ On Aug. 30, the Commission entered an Order reprimanding and assessing an administrative fine on the license to practice medicine in Alabama of **John P. Hagler, Jr., MD**, license number MD.6566, Montgomery, AL.

◆ On Aug. 30, the Commission entered an Order placing on indefinite probation the license to practice medicine or osteopathy in Alabama of **Mark Peter Koch, DO**, license number DO.322, Camden, AL, subject to certain conditions.

◆ On Aug. 30, the Commission entered an Order suspending the license to practice medicine in Alabama of **Kenneth E. Roberts, MD**, license number MD.9562, Dothan, AL.

◆ On Aug. 30, the Commission entered an Order placing on indefinite probation the license to practice medicine of **Bruce A. Williams, MD**, license number MD.10995, Birmingham, AL.

MLC – September 2012

◆ On Sept. 21, upon the Stipulation of the parties, the Commission entered a Consent Order reprimanding the license to practice medicine in Alabama of **Eugene A. Mangieri, MD**, license number MD.10801, Northport, AL, placing the license on probation for two years with conditions, and assessing an administrative fine.

BME – September 2012

◆ On Sept. 24, **Jeffrey Dean Voreis, MD**, license number MD.11280, Dadeville, AL, voluntarily surrendered

his Alabama Controlled Substances Certificate in Schedules II, IIN, III and IIIN, except for hospital and nursing home inpatient use only. Dr. Voreis remains authorized to prescribe in Schedules IV and V.

MLC – October 2012

◆ On Oct. 9, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Ashok Jagani, MD**, license number MD.22377, Northport, AL, with conditions, including controlled substance prescribing limited to Schedules IV and V except in a hospital setting.

◆ On Oct. 9, the Commission entered an Order approving the practice plan of **Mark Peter Koch, DO**, license number DO.322, Elba, AL.

◆ On Oct. 9, the Commission entered an Order reprimanding the license to practice medicine in Alabama of **W. Ricardo Montiel, MD**, license number MD.18168, Prattville, AL, assessing an administrative fine, and imposing other conditions.

BME – October 2012

◆ On Oct. 23, the Board issued an Order terminating the Voluntary Restriction on the certificate of qualification and license to practice medicine in Alabama of **William Richie Jordan, MD**, license number MD.13263, Smiths, AL, and restoring the certificate and license to full, unrestricted status.

◆ On Oct. 23, the Board entered an Order removing all restrictions from the certificate of qualification to practice medicine in Alabama of

Lloyd A. Manchikes, MD, license number MD.13075, Mobile, AL.

◆ On Oct. 23, the Board issued an Order denying the application for reinstatement of the certificate of qualification to practice medicine in Alabama of **Ricky Joe Nelson, MD**, license number MD.12557, Hanceville, AL.

◆ On Oct. 9, the Board issued an Order revoking the Alabama Controlled Substances Certificate of **Morris W. Cochran, MD**, license number ACSC.14439, Birmingham, AL.

◆ On Oct. 9, the Board issued an Order denying the application for rehearing concerning the revocation of the Alabama Controlled Substances Certificate of **Rodolfo M. Veluz, MD**, license number ACSC.9246, Irondale, AL.

◆ Effective Oct. 1, the certificate of qualification and license to practice medicine or osteopathy in Alabama of **Grant D. Geske, DO**, license number DO.1303, Birmingham, AL, is subject to a Voluntary Restriction.

MLC – November 2012

◆ On Nov. 2, the Commission entered an Order placing on indefinite probation the license to practice medicine in Alabama of **Muhammad Wasim Sadiq Ali, MD**, license number MD.22219, Jasper, AL.

◆ On Nov. 2, the Commission entered an Order removing all restrictions from the license to practice medicine in Alabama of **Lloyd A. Manchikes, MD**, license number MD.13075, Mobile AL.

see Public Actions, page 6



Alabama BME Newsletter and Report

Alabama Board of Medical Examiners
P.O. Box 946
Montgomery, AL 36101-0946
www.albme.org

PRESORTED
STANDARD
U.S. POSTAGE
PAID
Montgomery, AL
Permit No. 417

Look inside for important news
from the Board of Medical Examiners
that pertains to your license to practice
medicine in Alabama.



Follow the Board
on Twitter

[@AlaMedBd](https://twitter.com/AlaMedBd)

Receive alerts for new public actions,
agendas, newsletters and rules.

Change of Address

Alabama law 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.

All current licensees receive the Board of Medical Examiners *Newsletter and Report* at their address of record at no charge. Licensees may also choose to receive the newsletter by e-mail. Non-licensee subscriptions to the newsletter are by e-mail only. If you would like to receive the newsletter by e-mail, please send a request to masa@masalink.org.