

ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODE

CHAPTER 540-X-4
CONTROLLED SUBSTANCES CERTIFICATE

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<u>540-X-4-.01</u>	<u>Registration For Alabama Controlled Substances Certificate.</u>

(1) Every physician licensed to practice in Alabama who distributes, prescribes, or dispenses any controlled substance within Alabama or who proposes to engage in the distributing, prescribing or dispensing of any controlled substance within Alabama must obtain annually a registration certificate. The fee for such certificate is \$150.00, which includes the fee payable to the Alabama Department of Public Health Prescription Drug Monitoring Data Bank required by Code of Ala. 1975, §20-2-217, or as otherwise set by law.

(2) The requirement stated in paragraph (1) of obtaining a registration certificate is waived for the following physicians:

(a) Physicians employed by and working exclusively for the United States Department of Veteran's Affairs; and

(b) Medical residents for a period of eighteen months from the start date of the first year of the residency program.

1. At the end of the eighteenth month, the requirement stated in paragraph (1) shall apply.

2. Medical resident shall mean those medical residents in residency programs who are employed by or who are taking courses of instruction at the University of Alabama School of Medicine, the University of South Alabama College of Medicine, or such other medical schools or colleges, hospitals, or institutions in Alabama which may be approved by the Board of Medical Examiners.

3. A medical resident for whom the requirement of obtaining a registration certificate is waived shall perform his or her work within the facilities of the University of Alabama School of Medicine, the University of South Alabama College of Medicine, or such other institutions in Alabama which may be approved by the Board of Medical Examiners and as an adjunct to his or her course of study or training.

(3) Persons registered by the Board to distribute, prescribe, dispense or conduct research with controlled substances may possess, distribute, dispense or conduct research with those substances to the extent authorized by their registration and in conformity to any Board regulations and statutes governing controlled substances.

(4) A physician who applies for a waiver for exemption from the mandatory continuing education requirement under Rule 540-X-14-.04 shall, as a condition precedent to the granting of such waiver, surrender his or her controlled substance registration certificate to the Board of Medical Examiners.

(5) A physician who applies for annual renewal of his or her license to practice medicine under Section 34-24-337, Code of Ala. 1975, and in connection with that application claims exemption from the continuing medical education requirement by virtue of a waiver granted under Rule 540-X-14-.04 is ineligible to receive a controlled substance registration certificate so long as the waiver remains in effect.

(6) A physician who applies to the Board of Medical Examiners for termination of a waiver granted due to retirement status and who applies for a registration certificate shall, as a condition precedent to the issuance of the certificate, submit proof that he or she has satisfied the continuing medical education requirement established under Rule 540-X-14-.02.

Author: Alabama State Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-51.

History: Filed November 9, 1982 as Rule No. 540-X-2-.24.

Readopted: Filed February 8, 1983. **Rules reorganized**--rule number changed to 540-X-4-.01 (see conversion table at end of code): Filed June 14, 1984 (without publication in AAM).

Emergency rule filed August 22, 1986. **Amended:** Filed October 17, 1986. **Amended:** Filed May 20, 1996; effective June 24, 1996. **Amended:** Filed October 22, 1999; effective November 26, 1999. **Amended:** Filed July 19, 2007; effective August 19, 2007. **Amended:** Filed July 16, 2009; effective August 20, 2009. **Amended:** Filed February 17, 2010; effective March 24, 2010. **Amended:** Filed July 23, 2010; effective August 27, 2010. **Amended:** Published February 28, 2020; effective April 13, 2020.

540-X-4-.02 **Application For An Alabama Controlled Substances Certificate.** An example of the application for an Alabama Controlled Substances Certificate is contained in Appendix A of Chapter 4.

Author: Wendell R. Morgan

Statutory Authority: Code of Ala. 1975, §20-2-51, 34-24-53.

History: Filed November 9, 1982 as Rule No. 540-X-2-.25.

Readopted: Filed February 8, 1983. **Rules reorganized**--rule number changed to 540-X-4-.02 (see conversion table at end of code): Filed June 14, 1984 (without publication in AAM).

Amended: Filed February 21, 1986.

540-X-4-.03 **Renewal Of An Alabama Controlled Substances Certificate.**

(1) Renewal of an Alabama Controlled Substances Certificate shall be annually on or before December 31 of each year.

(2) An applicant for renewal of an Alabama Controlled Substances Certificate shall submit to the Board the required certificate fee of \$150.00.

(3) Before renewing an Alabama Controlled Substances Certificate, the applicant shall have a current registration to access the Controlled Substances Prescription Database established and maintained by the Alabama Department of Public Health.

(4) Before renewing an Alabama Controlled Substances Certificate, an applicant shall have a current and appropriate registration issued by the United States Drug Enforcement Agency.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-51, Act No. 2013-256.

History: New Rule: Filed November 14, 2013; effective December 19, 2013.

540-X-4-.04 Regulation Governing Maintenance Of Records And Inventories.

(1) Every physician and osteopath certified to order, prescribe, possess, distribute or dispense controlled substances by the Board shall be required to maintain the inventories, logs, and records prescribed in this rule.

(2) Inventory requirement. All controlled substances classified under Schedule II, IIN, III, IIIN, IV, and V of the Alabama Uniform Controlled Substances Act which are purchased and maintained in the office of the physician must be inventoried at least every two (2) years. This inventory shall account for all controlled substances purchased, maintained and dispensed in the office of the physician. This inventory requirement shall apply to Schedule II and IIN prepackaged samples and starter packs but does not apply to Schedule III, IIIN, IV, and V prepackaged samples and starter packs.

(3) Dispensing record. Every physician and osteopath who shall dispense Schedule II, IIN, III, IIIN controlled substances shall maintain a separate dispensing record of all such substances dispensed or distributed. The dispensing record shall contain the following information:

- (a) The date the controlled substance was dispensed;
- (b) The name and quantity of the controlled substance dispensed;
- (c) The method of administration of the controlled substance;
- (d) The name of the patient to whom the controlled substance was dispensed;
- (e) For all Schedule II amphetamines, amphetamine-like anorectic drugs, or sympathomimetic amine drugs dispensed in the treatment of narcolepsy, hyperkinesis, brain dysfunction, epilepsy or depression, dispensing records shall include the diagnosis and the reason for prescribing the Schedule II amphetamine.

(4) Labeling requirement. Every physician and osteopath who shall dispense any controlled substances classified under Schedules II, IIN, III, IIIN, IV and V of the Alabama Uniform Controlled Substances Act shall ensure that all such substances dispensed be labeled containing the following information:

- (a) The name of the patient to whom the controlled substance was dispensed;
- (b) The date that the controlled substance was dispensed;
- (c) The name and quantity of the controlled substance;
- (d) Instructions for taking or administering the controlled substance;
- (e) The name of the physician dispensing the controlled substance. The label required by this subsection shall be written in legible handwriting or typed and shall be permanently affixed to the package or container in which the controlled substance is dispensed. This labeling requirement shall not apply to prepackaged sample or starter packs in their original packages or containers.

(5) A physician or osteopath who prescribes a Schedule II amphetamine and/or a Schedule II amphetamine-like

anorectic drug and/or a Schedule II sympathomimetic amine drug or compound thereof and/or any salt, compound, isomer, derivative or preparation of the foregoing which are chemically equivalent thereto, and/or other non-narcotic Schedule II stimulant drugs, for the treatment of narcolepsy, hyperkinesia, brain dysfunction, epilepsy or depression as permitted by Code of Ala. 1975, §20-2-54(a) (as amended by Act No. 83-890), shall maintain a complete record of the treatment of the patient which must include documentation of the diagnosis and reason for prescribing the Schedule II amphetamine, the name, dose, strength, and quantity of the controlled substance prescribed and the date that the controlled substance was prescribed. The record required by this subsection may be maintained in the patient's medical records, provided that such medical records are maintained at the office of the physician and are available for inspection by the representatives of the Board of Medical Examiners.

(6) The inventory, separate dispensing record, and Schedule II amphetamine prescribing record required by this rule shall be maintained in the office of the physician or osteopath for a period of five (5) years from the date that the inventory is completed or the controlled substances are dispensed and shall be made available for inspection by representatives of the Board of Medical Examiners.

(7) Failure to maintain and make available for inspection the inventory and dispensing records and failure to adhere to the labeling provisions required by this rule shall be considered a failure to maintain effective controls to prevent the utilization of controlled substances for other than legitimate medical purposes and may be considered by the Board of Medical Examiners in determining whether a physician holding an Alabama Uniform Controlled Substance Registration Certificate has excessively dispensed controlled substances.

(8) 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 requirement to maintain and make available for inspection the inventory and dispensing records, and for each violation or failure to comply with the labeling requirements provided in this rule.

(9) Upon an initial determination by the Board that any physician may have violated the rules and regulations of the Board governing maintenance of records and inventories for controlled substances, 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, Code of Ala. 1975, §§41-22-1, et seq. 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 Code of Ala. 1975, §41-22-12.

(10) 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.

(11) 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.

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

Statutory Authority: Code of Ala. 1975, §§20-2-54 (as amended by Act No. 83-890); 20-2-56; Act No. 86-451 (Reg. Session 1986); 34-24-380; 34-24-382 (as amended by Act No. 2002-140).

History: Filed November 9, 1982 as Rule No. 540-X-2-.26.

Readopted: Filed February 8, 1983. **Repealed and new rule**

adopted in lieu thereof: Filed March 23, 1984. **Rules**

reorganized--rule number changed to 540-X-4-.03 (see conversion

table at end of code): Filed June 14, 1984 (without publication in AAM). **Amended:** Filed August 22, 1986. **Amended:** Filed August 22, 2002; effective September 26, 2002.

Ed. Note: Original Rule 540-X-4-.03, Regulation Governing Maintenance Of Records And Inventories, was renumbered to .04 as per certification filed November 14, 2013; effective December 19, 2013.

540-X-4-.05 Registration Of Dispensing Physicians And Osteopaths.

(1) Every dispensing physician, as defined by this rule, is hereby required to register with the State Board of Medical Examiners as a dispensing physician. Registration shall be accomplished on a form provided by the Board. After initially registering as a dispensing physician, it shall be the obligation of the registrant to advise the Board of any change in the practice location within the State of Alabama of that dispensing physician.

(2) For the purposes of this rule a "dispensing physician" shall mean any physician or osteopath licensed to practice medicine in Alabama who shall dispense or distribute to a patient for the patient's use any controlled substance, except prepackaged samples and/or starter packs, where such controlled substances are purchased by the physician or osteopath for resale to a patient whether or not a separate charge is made for the controlled substance. Prepackaged samples and starter packs shall mean those controlled substances which are packaged and labeled by the manufacturer in individual or small dosage units and which are intended to be distributed to patients for consumption or administration within a limited period of time. Controlled substances which are consumed by or which are administered to patients while being treated in the physician's office, clinic, hospital or other facility are not considered to be dispensed for the purposes of this rule. This registration requirement shall be applicable to all physicians or osteopaths who dispense or cause to be dispensed controlled substances for consumption or administration by patients off the premises of the clinic, hospital or other facility where the physician or osteopath practices, without respect to whether such controlled substances are purchased by an individual physician or osteopath, a professional association or professional corporation, a for-profit or not-for-profit corporation, a

hospital, clinic or other medical facility. This registration requirement shall not apply to the dispensing of controlled substances to patients treated in any hospital emergency room provided that (a) the patient has registered for treatment in the hospital emergency room and was treated by the emergency room physician on duty and (b) the controlled substances dispensed are subject to inventory, accounting and security controls and policies of the hospital pharmacy or the emergency room department. A controlled substance is any drug or substance listed in Schedules II through V of the Alabama Uniform Controlled Substance Act, Code of Ala. 1975, §§20-2-1, et seq.

(3) Within thirty (30) days after the effective date of this rule the Board of Medical Examiners shall cause a notice to be mailed to every licensed physician whose practice location is in the State of Alabama notifying them of the requirements of this rule and of the procedures for obtaining the required registration form. Every dispensing physician shall be required to file the registration form with the State Board of Medical Examiners within ninety (90) days of the effective date of this rule. Any physician or osteopath who on the effective date of this rule is not a dispensing physician but later becomes a dispensing physician is required to file the registration form with the Board within thirty (30) days of becoming a dispensing physician. On the effective date of this rule all physicians or osteopaths issued a certificate of qualification for licensure to practice medicine in Alabama will be provided with notice of the requirements of this rule.

(4) The form for registration of dispensing physicians is incorporated as Appendix C to Chapter 4.

(5) Any physician who acts as a "dispensing physician," as defined in this rule, and who has not registered with the Board as required by this rule may be assessed by the Board an administrative fine not to exceed Ten Thousand Dollars (\$10,000.00), in addition to any other penalty authorized pursuant to Code of Ala. 1975, §20-2-54.

(6) Every dispensing physician registered with the Board shall report controlled substances information to the Alabama Department of Public Health according to the requirements of Code of Ala. 1975, §20-2-213 and regulations promulgated by the Alabama Department of Public Health pursuant to Code of Ala. 1975, §20-2-210, et. seq., concerning the controlled substances prescription database.

(7) A dispensing physician registered with the Board may be assessed an administrative fine not to exceed Ten Thousand Dollars (\$10,000.00) for each failure to report to the Alabama Department of Public Health as required by this rule.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-50.

History: Filed September 19, 1986. **Amended:** Filed August 19, 1999; effective September 23, 1999. **Amended:** Filed April 13, 2006; effective May 18, 2006. **Amended:** Filed December 14, 2017; effective January 28, 2018.

Ed. Note: Original Rule 540-X-4-.04 was renumbered to .05 as per certification filed November 14, 2013; effective December 19, 2013.

540-X-4-.06 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.

(a) 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, Code of Ala. 1975, §§41-22-1, et seq. 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 Code of Ala. 1975, §41-22-12.

(b) 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.

(c) 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.

Authors: Wendell R. Morgan, Esq., Patricia E. Shaner, Esq., Attorneys for the Alabama Medical Examiners

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

History: Filed September 19, 1986. **Amended:** Filed August 22, 2002; effective September 26, 2002. **Amended:** Filed September 19, 2002; effective October 24, 2002.

Ed. Note: Original Rule 540-X-4-.05 was renumbered to .06 as per certification filed November 14, 2013; effective December 19, 2013.

540-X-4-.07 Emergency Prescription Refill.

(1) If a pharmacist received a request for a prescription refill, the original of which is maintained in the pharmacy files, and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72 hour supply of the prescribed medication, provided that:

(a) The prescription is not a medicinal agent listed in Schedule II appearing in Title 20 Chapter 2.

(b) The prescription is not a medicinal agent listed in Schedule III appearing in Title 20 Chapter 2.

(c) The medication is essential to the maintenance of life or the continuation of therapy in a chronic condition including but not limited to drugs listed in the following categories, according to the latest edition of Facts and Comparisons, U.S.P./N.F., P.D.R. or A.M.A. Drug evaluation:

1. Blood Modifiers
 - (i) Iron Products
 - (I) Oral Iron
 - (II) Parenteral Iron
 - (III) Iron Combinations (with Vitamins, with Liver, with B12 and Intrinsic Factor)
 - (ii) Folic Acid
 - (I) Leucovorin Calcium
 - (iii) Vitamin B12
 - (I) Cyanocobalamin
 - (II) Hydroxocobalamin

- (III) Liver Preparations
- (iii) Vitamin K
- (iv) Recombinant Human Erythropoietin
- (v) Colony Stimulating Factors
- (I) Filgrastim
- (II) Sargramostim
- (vi) Antiplatelet Agents
- (I) Dipyridamole
- (II) Ticlopidine
- (vii) Anticoagulants
- (I) Heparin
- (II) Coumarin and Indandione Derivatives
- (viii) Heparin Antagonist
- (I) Protamine Sulfate
- (ix) Tissue Plasminogen Activator
- (x) Thrombolytic Enzymes
- (xi) Hemorheologic Agent
- (xii) Antithrombin
- (xiii) Antihemophilic Products
- (I) Antihemophilic factor
- (II) Anti-inhibitor coagulant complex
- (III) Factor IX complex (Human)
- (xiv) Hemostatics

- (I) Systemic
- (II) Topical
- (xv) Plasma Protein Fractions
- (xvi) Dextran Adjunct
- (xvii) Plasma Expanders
- (xviii) Perfluorochemical Emulsion
- (xix) Hemin
- 2. Hormones
 - (i) Sex Hormones
 - (I) Estrogens
 - (II) Progestins
 - (III) Estrogens and Progestins, Combines
 - (IV) Oral Contraceptives
 - (V) Levonorgestrel Implant
 - (VI) Intrauterine Progesterone
 - (VII) Androgens
 - (VIII) Anabolic Steroids
 - (IX) Estrogen and Androgen Combinations
 - (X) Ovulation Stimulants
 - (XI) Gonadotropins
 - (XII) Chorionic Gonadotropin
 - (XIII) Gonadotropin Releasing Hormones
 - (XIX) Danazol
 - (ii) Growth Hormone

- (iii) Pituitary (Growth Hormone) Test
- (iv) Octreotide Acetate
- (v) Posterior Pituitary Hormones
 - (I) Vasopressin Derivatives
 - (II) Oxytocics
- (vi) Uterine Relaxant
- (vii) Abortifacients
 - (I) Prostaglandins
 - (II) Sodium Chloride
- (viii) Adrenal Cortical Steroids
 - (I) Corticotropin (ACTH)
 - (II) Mineralocorticoids
 - (III) Glucocorticoids
- (ix) Adrenal Steroid Inhibitors
- (x) Pituitary Function Test
- (xi) Antidiabetic Agents
 - (I) Insulin
 - (II) Sulfonylureas
- (xi) Glucose Elevating Agents
 - (I) Glucagon
 - (II) Diazoxide
 - (III) Glucose
- (xii) Alglucerase

- (xiii) Thyroid Drugs
- (I) Thyroid Hormones
- (II) Iodine Products
- (III) Antithyroid Agents
- (xix) Calcitonin
- (xv) Etidronate Disodium
- (xvi) Gallium Nitrate
- 3. Diuretics and Cardiovasculars
 - (i) Diuretics
 - (I) Carbonic Anhydrase Inhibitors
 - (II) Thiazides and Related Diuretics
 - (III) Loop Diuretics
 - (IV) Potassium Sparing Diuretics
 - (V) Diuretic Combinations
 - (VI) Osmotic Diuretics
 - (VII) Nonprescription Diuretics
 - (ii) Cardiac Glycosides
 - (iii) Amrinone
 - (iv) Antianginal Agents
 - (I) Combinations
 - (v) Antiarrhythmic Agents
 - (vi) Calcium Channel Blocking Agents
 - (vii) Peripheral Vasodilators
 - (I) Combinations

- (viii) Drugs used in Shock
- (ix) Beta-Adrenergic Blocking Agents
- (x) Alpha-Beta Adrenergic Blocking Agents
- (xi) Antihypertensives
- (I) Antiadrenergic Agents
- I. Centrally Acting
- II. Peripherally Acting
- (II) Vasodilators
- (III) Angiotensin Converting Enzyme Inhibitors
- (IV) Agents for Pheochromocytoma
- (V) Agents for Hypertensive Emergencies
- (VI) Miscellaneous Agents
- (VII) Combinations
- (xii) Potassium Removing Agents
- (xiii) Cardioplegia Solution
- (xix) Salt Substitutes
- (xv) Edentate Disodium
- (xvi) Antihyperlipidemic Agents
- 4. Respiratory Drugs
- (i) Bronchodilators
- (I) Sympathomimetics;
- (II) Xanthine Derivatives
- (ii) Respiratory Inhalant Products

- (I) Corticosteroids
- (II) Acetylcysteine
- (III) Atropine Sulfate
- (IV) Ipratropium Bromide
- (V) Cromolyn Sodium
- (iii) Nasal Decongestants
- (I) Combinations
- (iv) Intranasal Steroids
- (v) Alpha Proteinase Inhibitor
- (vi) Antihistamines
- (I) Miscellaneous Preparations
- (II) Combined Preparations
- (vii) Antitussive's
- (I) Narcotic
- (II) Non-narcotic
- (viii) Expectorants
- (I) Miscellaneous Preparations
- (ix) Respiratory Combination Products
- (I) Anti-asthmatic Combinations
- I. Xanthine Combinations
- A. Capsules and Tablets
- B. Liquids
- II. Xanthine Sympathomimetic Combinations
- A. Capsules and Tablets

- B. Liquids
 - (x) Upper Respiratory Combinations
 - (I) Decongestant Combinations
 - (II) Antihistamine and Analgesic Combinations
 - (III) Decongestants and Antihistamines
- I. Sustained Release
- II. Capsules and Tablets
- III. Liquids
- IV. Miscellaneous
 - (IV) Decongestant, Antihistamine and Analgesic Combinations
 - (V) Decongestant, Antihistamine and Anticholinergic Combinations
 - (VI) Cough Preparations
 - I. Antitussive Combinations
 - A. Capsules and Tablets
 - B. Liquids
 - II. Expectorant Combinations
 - A. Capsules and Tablets
 - B. Liquids
 - III. Antitussives and Expectorants
 - A. Narcotic
 - B. Non-narcotic Antitussive and Expectorant
 - IV. Antitussive and Expectorant Combinations

- A. With Decongestants
- B. With Antihistamines
- C. With Decongestants and Antihistamines
- V. Pediatric Cough Preparations
- 5. Central Nervous System Drugs
 - (i) CNS Stimulants
 - (I) Analeptics
 - (II) Amphetamines
 - (III) Anorexiant
 - (IV) Non-prescription Diet Aids
 - (ii) Analgesics
 - (I) Narcotic Agonist Analgesics
 - (II) Narcotic Analgesic Combinations
 - (III) Narcotic Agonist-Antagonist Analgesics
 - (IV) Other Central Analgesics
 - (V) Acetaminophen
 - (VI) Salicylates
 - (VII) Non-narcotic Analgesic Combinations
 - (VIII) Nonsteroidal Anti-Inflammatory Agents
 - (IX) Antirheumatic Agents
 - (X) Agents for Gout
 - (XI) Agents for Migraine
- I. Combinations
 - (iii) Antiemetic/Antivertigo Agents

- (iv) Psychotherapeutic Drugs
 - (I) Antianxiety Agents
 - (II) Antidepressants
 - (III) Antipsychotic Agents
 - (IV) Miscellaneous Psychotherapeutic Agents
 - (V) Sedative and Hypnotic
 - (VI) Non-barbiturates
 - (VII) Nonprescription Sleep Aids
 - (VIII) Barbiturates
- (vi) General Anesthetics
 - (I) Barbiturates
 - (II) Non-barbiturates
 - (III) Gases
 - (IV) Volatile Liquids
- (vii) Anticonvulsant
- (viii) Muscle Relaxants
 - (I) Adjuncts to Anesthesia
 - (II) Skeletal
 - (III) Combinations
- (ix) Anti-parkinson Agents;
- 6. Gastrointestinal Drugs
 - (i) Antacids
 - (I) Combinations

- (ii) Sucralfate
- (iii) Gastrointestinal Anticholinergic/Antispasmodics
 - (I) Combinations
- (iv) Histamine H2 Antagonists
- (v) Prostaglandins
- (vi) Antiflatulents
- (vii) GI Stimulants
 - (I) Metoclopramide
 - (II) Dexpanthenol
- (viii) Digestive Enzymes
- (ix) Gastric Acidifiers
- (x) Cholagogues
 - (I) Combinations
- (xi) Hydrocholeretics
 - (I) Combinations
- (xii) Miscellaneous Digestive Products
- (xiii) Gallstone Solubilizing Agents
 - (I) Chenodiol
 - (II) Ursodiol
 - (III) Monoctanoic
- (xiv) Laxatives
 - (I) Saline
 - (II) Stimulant
 - (III) Bulk
 - (IV) Emollient

- (V) Fecal Softeners
- (VI) Hyperosmolar Agents
- (VII) Enemas
- (VIII) CO₂ Releasing Suppositories
- (IX) Bowel Evacuants
- (X) Lactulose
- (XI) Combinations
- (XV) Antidiarrheal
- (I) Diphenoxylate/Atropine
- (II) Loperamide
- (III) Bismuth Subsalicylate
- (IV) Combinations
- (xvi) Mesalamine
- 7. Antineoplastic Agents
 - (i) Chemotherapeutic Regimens
 - (ii) Alkylating Agents
 - (I) Nitrogen Mustards
 - I. Mechlorethamine HCl
 - II. Chlorambucil
 - III. Cyclophosphamide
 - IV. Uracil Mustard
 - (II) Nitrosoureas
 - I. Lomustine

- II. Carmustine
- III. Streptozocin
- (III) Thiotepa
- (IV) Busulfan
- (V) Pipobroman
- (VI) Cisplatin
- (iii) Antimetabolite
- (I) Methotrexate
- (II) Fluorouracil and Floxuridine
- (III) Cytarabine
- (IV) Mercaptopurine
- (V) Thioguanine
- (iv) Hormones
- (I) Androgens
- I. Testolactone
- (II) Progestins
- I. Megestrol Acetate
- II. Medroxyprogesterone Acetate
- (III) Estrogens
- I. Diethylstilbestrol Diphosphate
- II. Polyestradiol Phosphate
- (IV) Estrogen/Nitrogen Mustard
- I. Estramustine Phosphate
- (V) Anti-estrogen

- I. Tamoxifen
- (VI) Gonadotropin Hormone-Releasing Antigen
- I. Leuprolide Acetate
- (v) Antibiotics
- (I) Bleomycin Sulfate
- (II) Doxorubicin HCl
- (III) Daunorubicin HCl
- (IV) Mitoxantrone HCl
- (V) Mitomycin
- (VI) Dactinomycin
- (VII) Picamycin
- (vi) Mitotic Inhibitors
- (I) Etoposide
- (II) Vincristine Sulfate
- (III) Vinblastine Sulfate
- (vi) Radiopharmaceutical
- (I) Sodium Iodide I
- (II) Sodium Phosphate P
- (III) Chromic Phosphate P
- (vii) Miscellaneous
- (I) Interferon Alfa-2a
- (II) Interferon Alfa-2b
- (III) Hydroxyurea

- (IV) Procarbazine HCI
- (V) Dacarbazine
- (VI) Mitotane
- (VII) Asparaginase
- (viii) NCI Investigational Agents

(d) The dispensing pharmacist creates a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations.

(e) The dispensing pharmacist notifies the prescriber, orally or in writing, of the emergency dispensing within seventy-two (72) hours after such dispensing.

(2) This rule is adopted jointly by the Board of Pharmacy and the Board of Medical Examiners.

Author: Patricia E. Shaner, Attorney for the Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §§34-23-75, 34-24-53.

History: Filed: December 17, 1992 (for publication). Refiled for Publication: August 11, 1993. **Approved/Adopted:** October 20, 1993. Effective Date: November 25, 1993. (This rule has been jointly adopted by the BME and the Pharmacy Board.)

Ed. Note: Original Rule 540-X-4-.06 was renumbered to .07 as per certification filed November 14, 2013; effective December 19, 2013.

540-X-4-.08 Requirements 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 tolerance, dependence or 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 requirements 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. 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. 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 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 MEDICAL

KNOWLEDGE OF THE TREATMENT OF PAIN. ALL SUCH PRESCRIBING MUST BE BASED ON CLEAR DOCUMENTATION AND IN COMPLIANCE WITH APPLICABLE STATE OR FEDERAL LAW.

(f) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation. The goal is to reduce pain and/or improve patients' function.

(g) Physicians are referred to the Federation of State Medical Boards' Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013, as amended from time to time, and the Drug Enforcement Administration Office of Diversion Control manual, Narcotic Treatment Programs Best Practice Guidelines, as amended from time to time.

(2) Requirements. The Board requires the following when a physician evaluates the use of controlled substances for pain control:

(a) Evaluation of the Patient. A 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 should also 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 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 the patient. Alternative non-opioid treatment modalities or a rehabilitation program may be necessary and should be considered.

(c) Informed Consent and Agreement for Treatment. The physician shall 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. Written agreements between physician and

patient outlining patient responsibilities should be utilized for all patients with chronic pain, and should include:

1. Drug screening with appropriate confirmation;
2. A prescription refill policy; and
3. Reasons for which drug therapy may be discontinued (e.g., violation of agreement).
4. The patient should receive prescriptions from one physician and one pharmacy where possible.

(d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. The physician shall 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 co-morbid 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 shall 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.

These records shall 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. (3)

Definitions. For the purposes of this rule, the following terms are defined as follows:

(a) Acute Pain. The normal, predicted, time-limited physiological response to nociceptive stimuli such as injury, trauma or illness.

(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. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Chronic Pain. A state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months), and which may or may not be associated with an acute or chronic pathological process that causes continuous or intermittent pain over a period of months or years.

(d) Substance Abuse. Substance abuse is a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances.

(e) Tolerance. Tolerance is the need for greatly increased amounts of a substance to achieve intoxication (or the desired effect) or a markedly diminished effect with continued use of the same amount of the substance.

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

Statutory Authority: Code of Ala. 1975, §34-24-53.

History: New Rule: Filed March 20, 1995; effective April 24, 1995. **Repealed and New Rule:** Filed

December 15, 1999; effective January 19, 2000. **Repealed and New Rule:** December 15, 1999; effective January 19, 2000. **Amended:** Filed November 14, 2013; effective December 19, 2013.

Ed. Note: Original Rule 540-X-4-.07 was renumbered to .08 as per certification filed November 14, 2013; effective December 19, 2013.

540-X-4-.09 **Risk And Abuse Mitigation Strategies.**

(1) The Board recognizes that all controlled substances, including but not limited to, opiates, benzodiazepines, stimulants, anticonvulsants, and sedative hypnotics, have a risk of addiction, misuse, and diversion. It is the opinion of the Board that the best practice when prescribing controlled substances shall include medically appropriate risk and abuse mitigation strategies, which will vary from patient to patient. Additional care should be used by practitioners when prescribing medication to a patient from multiple controlled substance drug classes.

(2) Every practitioner shall provide his or her patient with risk education prior to initiating controlled substances therapy and prior to continuing the controlled substances therapy initiated by another practitioner.

(3) Every practitioner shall utilize medically appropriate risk and abuse mitigation strategies when prescribing controlled substances. Examples of risk and abuse mitigation strategies include, but are not limited to:

- (a) Pill counts;
- (b) Urine drug screening;
- (c) PDMP checks;
- (d) Consideration of abuse-deterrent medications;
- (e) Monitoring the patient for aberrant behavior;

(f) Using validated risk-assessment tools, examples of which shall be maintained by the Board; and

(g) Co-prescribing naloxone to patients receiving opioid prescriptions when determined to be appropriate in the clinical judgment of the treating practitioner.

(4) The Board recognizes that the best available research demonstrates that the risk of adverse events occurring in patients who use controlled substances to treat pain increases as dosage increases. The Board adopts the "Morphine Milligram Equivalency" ("MME") daily standard as set out by the Centers for Disease Control and Prevention ("CDC") for calculating the morphine equivalence of opioid dosages. The Board further adopts the "Lorazepam Milligram Equivalency" ("LME") daily standard for calculating sedative dosing when using the Alabama Prescription Drug Monitoring Program.

(5) For the purpose of preventing controlled substance diversion, abuse, misuse, addiction, and doctor-shopping, the Board sets forth the following requirements for the use of Alabama's Prescription Drug Monitoring Program (PDMP):

(a) For controlled substance prescriptions totaling less than 30 MME or 3 LME per day, physicians are expected to use the PDMP in a manner consistent with good clinical practice.

(b) When prescribing to a patient controlled substances of more than 30 MME or 3 LME per day, physicians shall review that patient's prescribing history through the PDMP at least two (2) times per year, and each physician is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

(c) Physicians shall query the PDMP to review a patient's prescribing history every time a prescription for more than 90 MME or 5 LME per day is written, on the same day the prescription is written.

(6) Exemptions: The Board's PDMP requirements do not apply to physicians writing controlled substance prescriptions for:

(a) Nursing home patients;

- (b) Hospice patients, where the prescription indicates hospice on the physical prescription;
- (c) When treating a patient for active, malignant pain; or
- (d) Intra-operative patient care.
- (7) Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, physicians should reconsider a patient's existing benzodiazepine prescriptions or decline to add one when prescribing an opioid and consider alternative forms of treatment.
- (8) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) credits of AMA PRA Category 1™ continuing medical education (CME) in controlled substance prescribing every two (2) years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.
- (9) A violation of this rule is grounds for the assessment of a fine and for the suspension, restriction, or revocation of a physician's Alabama Controlled Substances Certificate or license to practice medicine.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §§34-24-53, 34-24-336, 20-2-54.1, 20-2-214(2).

History: New Rule: Filed January 23, 2017; effective March 9, 2017. **Amended:** Filed July 19, 2018; effective September 2, 2018. **Amended:** Filed June 24, 2019; effective August 8, 2019.

Ed. Note:

540-X-4-.07 Schedule Of Administrative Fines. (Repealed)

Author: Wendell R. Morgan

Statutory Authority: Code of Ala. 1975, §§34-24-380 through 34-24-384.

History: Filed October 17, 1986. **Repealed:** Filed August 22, 2002; effective September 26, 2002.