### TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>540-X-4-.01</td>
<td><strong>Registration For Alabama Controlled Substances Certificate</strong></td>
</tr>
<tr>
<td>540-X-4-.02</td>
<td><strong>Application For An Alabama Controlled Substances Certificate</strong></td>
</tr>
<tr>
<td>540-X-4-.03</td>
<td><strong>Regulation Governing Maintenance Of Records And Inventories</strong></td>
</tr>
<tr>
<td>540-X-4-.04</td>
<td><strong>Registration Of Dispensing Physicians And Osteopaths</strong></td>
</tr>
<tr>
<td>540-X-4-.05</td>
<td><strong>Controlled Substances Prescription Guidelines For Physicians</strong></td>
</tr>
<tr>
<td>540-X-4-.06</td>
<td><strong>Schedule Of Administrative Fines</strong></td>
</tr>
<tr>
<td></td>
<td><em>(Repealed 9/26/02)</em></td>
</tr>
<tr>
<td>540-X-4-.07</td>
<td><strong>Emergency Prescription Refill</strong></td>
</tr>
<tr>
<td>540-X-4-.08</td>
<td><strong>Guidelines For The Use Of Controlled Substances For The Treatment Of Pain</strong></td>
</tr>
</tbody>
</table>

#### 540-X-4-.01 Registration For Alabama Controlled Substances Certificate

(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 $140.00, or as otherwise set by law.

(2) If a physician or osteopath receives an initial Alabama Controlled Substances Certificate on or after November 23rd of any year, it will be issued at no charge for the remainder of the year.

(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  

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  
540-X-4-.03 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, hyperkinesis, 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


540-X-4-.04 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
Medical Examiners

Chapter 540-X-4

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 B 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.
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.

(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


540-X-4-.06 Schedule Of Administrative Fines. (Repealed)

Author: Wendell R. Morgan


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) Ipratroplum 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) Anorexiants
   (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) Choleretics
(xi) Hydrocholeretics
(I) Combinations
(xii) Miscellaneous Digestive Products
(xiii) Gallstone Solubilizing Agents
(I) Chenodiol
(II) Ursodiol
(III) Monoctanoin
(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 HCI
   (III) Daunorubicin HCI
   (IV) Mitoxantrone HCI
   (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 Alga-2b
   (III) Hydroxyurea
(IV) Procarbazine HCl
(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


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.)

540-X-4-.08 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.


(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 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 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.

(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.

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