ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODE

CHAPTER 540-X-4
CONTROLLED SUBSTANCES CERTIFICATE

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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 $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.

(7) To maintain an active Alabama Controlled Substances Certificate, a physician must maintain an active registration issued by the United States Drug Enforcement Administration ("DEA") and which complies with DEA's rules and regulations. A physician who applies for an Alabama Controlled Substances Certificate shall provide the Board with the DEA registration number authorizing his or her prescribing of controlled substances in Alabama at the time of application, or, if no such registration has been issued, shall provide the Board with the DEA registration number as soon as it is issued. Each physician who is issued an Alabama Controlled Substances Certificate shall provide a copy of the DEA registration certificate to the Board immediately upon renewal of the registration. Each physician who obtains additional DEA registrations of multiple dispensing sites shall provide the Board with the additional DEA registration number(s) and a copy of the DEA registration certificate as soon as it is issued and immediately upon renewal.

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. **Amended:** Published December 30, 2021; effective February 13, 2022.

540-X-4-.02 Application For An Alabama Controlled Substances Certificate.

An applicant for an Alabama Controlled Substances Certificate shall disclose whether:

(1) Applicant's privilege for dispensing or prescribing controlled substances has ever been suspended, restricted, voluntarily surrendered while under investigation or revoked in any state.

(2) Applicant has ever been convicted of any state or federal crime relating to any controlled substance or driving under the influence (DUI).

(3) Any Federal Drug Enforcement Administration registration ever held by applicant has ever been suspended, restricted, revoked, or voluntarily surrendered while under investigation.

(4) Applicant's staff privileges at any hospitals have ever been suspended, restricted, or revoked for any reason related to the prescribing or dispensing of controlled substances.

(5) Applicant is currently suffering from any condition that impairs your judgment or that would otherwise adversely affect your ability to practice medicine in a competent, ethical, and professional manner.

(6) Within the past five years, applicant has raised the issue of any physical or psychiatric health disorder as a defense, mitigation, or explanation for your actions during any administrative or judicial proceeding or investigation; any inquiry or other proceeding; or any proposed termination by an educational institution; employer; government agency; professional organization; or licensing authority.

(7) Applicant attests to this statement:

The Board recognizes that licensees encounter potentially impairing health conditions just as their patients and other health care providers do, including psychiatric or physical illnesses which may impact cognition, as well as substance use disorders. The Board expects its licensees to address their health concerns, both mental and physical, in a timely manner to ensure patient safety. Licensees should seek appropriate medical care and should limit their medical practice when appropriate and as needed. The Board encourages licensees to utilize the services of the Alabama Professionals Health Program, a physician advocacy organization dedicated to improving the health and wellness of medical professionals in a confidential manner. The failure to adequately address a health condition, where the licensee is unable to practice medicine with reasonable skill and safety to patients, can result in the Board taking action against the license to practice medicine.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §20-2-51.
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. **Amended:** Published December 30, 2022;

effective February 13, 2023. **Amended:** Published March 31, 2025; effective May 15, 2025.

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 Administration.

(5) The applicant shall disclose whether:

(a) Applicant's privilege for dispensing or prescribing controlled substances has ever been suspended, restricted, voluntarily surrendered while under investigation, or revoked in any state.

(b) Applicant has ever been convicted of any state or federal crime relating to any controlled substance or driving under the influence (DUI).

(c) Any Federal Drug Enforcement Administration registration ever held by applicant has ever been suspended, restricted, revoked or voluntarily surrendered while under investigation.

(d) Applicant's staff privileges at any hospitals have ever been suspended, restricted, or revoked for any reason related to the prescribing or dispensing of controlled substances.

(e) Applicant is currently suffering from any condition that impairs their judgment or that would otherwise adversely affect their ability to practice medicine in a competent, ethical, and professional manner.

(f) Within the past five years, applicant has raised the issue of any physical or psychiatric health disorder as a defense, mitigation, or explanation for their actions during any administrative or judicial proceeding or investigation; any inquiry or other proceeding; or any proposed termination by an

educational institution; employer; government agency; professional organization; or licensing authority.

(g) Applicant has read and understood the following statement:

The Board recognizes that licensees encounter potentially impairing health conditions just as their patients and other health care providers do, including psychiatric or physical illnesses which may impact cognition, as well as substance use disorders. The Board expects its licensees to address their health concerns, both mental and physical, in a timely manner to ensure patient safety. Licensees should seek appropriate medical care and should limit their medical practice when appropriate and as needed. The Board encourages licensees to utilize the services of the Alabama Professionals Health Program, a physician advocacy organization dedicated to improving the health and wellness of medical professionals in a confidential manner. The failure to adequately address a health condition, where the licensee is unable to practice medicine with reasonable skill and safety to patients, can result in the Board taking action against the license to practice medicine.

(h) Applicant dispenses controlled substances, other than pharmaceutical samples, from any practice location.

Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §20-2-51, Act No. 2013-256 (Amendment to §20-2-214).
History: **New Rule:** Filed November 14, 2013; effective December 19, 2013. **Amended:** Published December 30, 2022; effective February 13, 2023. **Amended:** Published March 31, 2025; effective May 15, 2025.

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-1ike 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-1ike 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.
Author: 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.

(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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) The form for registration of dispensing physicians shall elicit the following information:

(a) Physician name and license number;

(b) Primary practice/dispensing location;

(c) Any and all additional practice/dispensing locations;

(d) Primary practice/dispensing location DEA number and expiration date.

(9) 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.

(10) 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.

(11) 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. **Amended:** Published December 30, 2022; effective February 13, 2023.

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 ensuring 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.

Author: 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 receives a request for a prescription refill, 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 or the smallest dispensable package size if a 72 hour supply is not readily available, under the following conditions:

(a) The prescription is not a medicinal agent listed in Schedule I or II pursuant to Title 20, Chapter 2, or the controlled substance list for Schedule I or II maintained by the State Board of Health.

(b) The medication is essential to the maintenance of life or the continuation of therapy and in the pharmacist's professional judgement, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(c) The pharmacist has a record of a prescription at the pharmacy or has been presented proof of a prescription filled within the last 90 days in the name of the patient for whom the request of the emergency supply is being made.

(d) A pharmacist or pharmacy shall not dispense or sell the same drug to the same patient, as provided in the section, more than one time in any 12-month period.

(e) The pharmacist must inform the patient or the patient's representative at the time of dispensing that the refill is being provided without the practitioner's authorization, and that practitioner authorization is required for any future refill.

(f) The dispensing pharmacist shall create a written prescription order containing all of the prescription information required by federal and state statutes, rules and regulations and shall also include the statement "Emergency Fill".

(g) The dispensing pharmacist shall notify the prescriber, orally or in writing, of the emergency dispensing within twenty-four (24) 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.) **Amended:** Published November 30, 2023; effective January 14, 2024.

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 (REPEALED).

Author: 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. **Repealed:** Published July 31, 2023; effective September 14, 2023.

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.

540-X-4-Appendix-A Application For Controlled Substance Registration Certificate (Repealed 2/13/23).

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CHAPTER 4 - APPENDIX A
APPLICATION FOR CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE
(REPEALED 2/13/23)

Author:
Statutory Authority:
History:

540-X-4-Appendix-B Alabama Controlled Substance Certificate Registration Renewal (Repealed 2/13/23).

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CHAPTER 4 - APPENDIX B
CONTROLLED SUBSTANCES CERTIFICATE REGISTRATION RENEWAL
(REPEALED 2/13/23)

Author:
Statutory Authority:
History:

540-X-4-Appendix-C **Dispensing Physician's Registration Form (Repealed 2/13/23).**

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CHAPTER 4 - APPENDIX C
DISPENSING PHYSICIAN REGISTRATION FORM
(REPEALED 2/13/23)

Author: Board of Medical Examiners
Statutory Authority:
History: Amended (Appendices A and B): Filed October 21, 2005; effective November 25, 2005. **Amended (Appendix A):** Filed November 13, 2007; effective December 18, 2007. **Amended:** Filed November 14, 2013; effective December 19, 2013. **Repealed and New Rule:** Filed July 20, 2017; effective September 3, 2017. **New Rule (Appendix C only):** Filed December 14, 2017; effective January 28, 2018. **Amended (Appendix A and B only):** Filed February 27, 2018; effective April 14, 2018. **Amended (Appendix A only):** Filed August 22, 2018; effective October 6, 2018. **Amended (Appendix C only):** Published December 31, 2019; effective February 14, 2020. **Repealed (Appendices A - C):** Published December 30, 2022; effective February 13, 2023.

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.