CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on the 15th day of December, 2021, and filed with the agency secretary on the 15th day of December, 2021.

AGENCY NAME: Alabama State Board of Medical Examiners

____X____ Amendment _______ New _______ Repeal (Mark appropriate space)

Rule No. 540-X-4-.01
(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Registration for Alabama Controlled Substances Certificate

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted without changes from the proposal. No comments were received.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XL, ISSUE NO. 1, AAM, DATED OCTOBER 29, 2021.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-51(d) and 34-24-53

(Date Filed)
(For LRS Use Only)

Certifying Officer or his or her Deputy

NOTE: In accordance with §41 22.6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.
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 Ala. Code § 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 Alabama 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.
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 for 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 Board of Medical Examiners
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AGENCY NAME: Alabama State Board of Medical Examiners

___X___Amendment _______New _______Repeal (Mark appropriate space)

Rule No. 540-X-5-.03
(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Revocation or Suspension of an Alabama Controlled Substances Certificate – Grounds and Procedures Generally

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted without changes from the proposal. No comments were received.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XL, ISSUE NO. 1, AAM, DATED OCTOBER 29, 2021.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-54; 20-2-71; 34-24-380(b)

(Date Filed)
(For LRS Use Only)

Certifying Officer or his or her Deputy

NOTE: In accordance with §41 22 6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.
540-X-5-.03 Revocation or Suspension of an Alabama Controlled Substances Certificate Registration - Grounds and Procedures Generally.

(1) A registration under specified laws to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Board upon a finding that the registrant;

(a) Has furnished false or fraudulent material information in any application filed under this article;

(b) Has been convicted of a crime under any state or federal law relating to any controlled substance;

(c) Has had his federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances;

(d) Has violated the provisions of Chapter 23 of Title 34 of the Code of Alabama, or;

(e) Has, in the opinion of the Board, excessively dispensed controlled substances for any of his patients.

1. A registrant may be considered to have excessively dispensed controlled substances if the Board finds that either the controlled substances were dispensed for no legitimate medical purpose, or that the amount of controlled substances dispensed by the registrant is not reasonably related to the proper medical management of the patient’s illness or conditions. Drug addiction shall not be considered an illness or condition which would justify continued dispensing of controlled substances, except in gradually decreasing dosages administered to the patient for the purpose of curing the addiction.
2. A registrant who is a physician licensed to practice medicine in the state of Alabama may be considered to have excessively dispensed controlled substances if he or she prescribes, orders, dispenses, administers, supplies or otherwise distributes any Schedule II amphetamine and/or Schedule II amphetamine like anorectic drug, and/or 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, which drugs or compounds are classified under Schedule II of the Alabama Uniform Controlled Substances Act, § 20-2-24, Code of Alabama, 1975, to any person except for the therapeutic treatment of:

(i) Narcolepsy

(ii) Hyperkinesis

(iii) Brain dysfunction of sufficiently specific diagnosis (such as Attention Deficit Disorder or Attention Deficit and Hyperactivity Disorder), or etiology which clearly indicates the need for these substances in treatment or control

(iv) Epilepsy

(v) Differential psychiatric evaluation of clinically significant depression provided however, that such treatment shall not extend beyond a period of thirty (30) days unless the patient is referred to a licensed practitioner specializing in the treatment of depression

(vi) Clinically significant depression shown to be refractory to other therapeutic modalities provided however, that such treatment shall not extend beyond a period of thirty (30) days unless the patient is referred to a licensed practitioner specializing in the
treatment of depression; or for the clinical investigation of the effects of such drugs or compounds, in which case an investigative protocol must be submitted to and reviewed and approved by the State Board of Medical Examiners before the investigation has begun. A physician prescribing, ordering or otherwise distributing the controlled substances listed above in the manner permitted by this subsection shall maintain a complete record which must include documentation of the diagnosis and reason for prescribing, the name, dose, strength, and quantity of the drug, and the date prescribed or distributed. The records required under this subsection shall be made available for inspection by the certifying board or its authorized representative upon request. Those Schedule II stimulant drugs enumerated above shall not be dispensed or prescribed for the treatment or control of exogenous obesity.

(f) Has violated any duly adopted rule or regulation of the Board of Medical Examiners pertaining to the possession, maintenance, dispensing, prescribing or distribution of any controlled substance.

(g) Has dispensed, prescribed or distributed controlled substances not authorized by his registration certificate.

(h) Has failed to maintain a registration with the U.S. Drug Enforcement Administration, has voluntarily surrendered a DEA registration or had a registration revoked.

(2) The Board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

(3) In addition to the penalty of suspension or revocation the Board may
assess an administrative fine not to exceed ten thousand dollars ($10,000.00) for each violation of any of the offenses stated in Rule 540-X-5-.03(1).

(4) All administrative 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 an appeal is instituted pursuant to §20-2-53 Code of Alabama, 1975, pertaining to appeals from decisions of the Board of Medical Examiners as a certifying Board under the Alabama Uniform Controlled Substances Act, in which event the fine is due and payable to the Board thirty (30) days after the final disposition of the appeal. When a fine has been assessed and is not subject to appeal, the name of the physician against whom the fine was assessed 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.

(5) 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.

(6) Administrative Costs:

(a) If the Board finds that a registrant is guilty of any offense stated in Rule 540-X-5-.03(1), the Board may order that administrative costs be assessed against and paid by the registrant.

(b) Administrative costs are the actual costs, fees and expenses incurred by the Board in connection with any Board proceeding resulting in a finding that the registrant has violated any provision of Rule 540-X-5-.03(1) and include the following:
1. Costs of independent medical review and expert testimony.
2. Reasonable and necessary attorney fees and expenses.
3. Travel expenses for Board staff.
5. Deposition costs, court reporter fees and costs, and transcript costs.
6. Witness fees and expenses.
7. Fees and costs for necessary interpreter services.
8. Fees and expenses for necessary consultants.

(c) Claims for administrative costs shall be submitted for review by the Board pursuant to a verified bill of costs on a form approved by the Board. The bill of costs shall be filed with the Board Secretary within fourteen (14) days from the date of any order assessing costs against the registrant. Any ruling on administrative costs shall be made by the Board at the scheduled monthly meeting following submission of the bill of costs.

(d) Payment of the administrative costs ordered by the Board shall be made and enforced in the same manner as an administrative fine as stated in Rule 540-X-5-.03(4).

(7) If the Board suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon
a revocation order becoming final, all controlled substances may be forfeited to the state.

(8) The Board shall promptly notify the Drug Enforcement Administration of all orders suspending or revoking registration and all forfeitures of controlled substances.

(9) For the purpose of the treatment of clinically significant depression as outlined in rule 540-X-5-.03(1)(e) 2.(v) and clinically significant depression shown to be refractory to other therapeutic modalities as outlined in rule 540-X-5-.03(1)(e)2.(vi) above when a diagnosis of clinically significant depression has been confirmed by a licensed practitioner specializing in the treatment of depression (as that term is defined in these rules) and the practitioner has recommended the use of or continuation of a Schedule II amphetamine, amphetamine like anorectic drug, sympathomimetic amine drug, or other Schedule II stimulant drug for the therapeutic treatment of the depression then such drug or drugs may be prescribed by the patients regular or attending physician for such period of time as is required to remedied the condition being treated.

Author: Alabama State Board of Medical Examiners
Statutory Authority: Code of Alabama 1975, §§ 20-2-54; 20-2-71; 34-24-380(b)