

APA-1
6/93

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-5-.03
Rule Title: Revocation or Suspension of an Alabama Controlled Substances Certificate Registration -
Grounds and Procedures Generally

New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

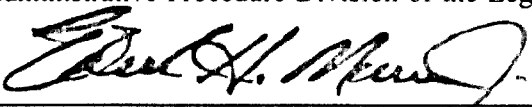
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer  REC'D & FILED

Date: January 22, 2018 JAN 22 2018

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6/93

**ALABAMA STATE BOARD
OF MEDICAL EXAMINERS**

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-5-.03, Revocation or Suspension of an Alabama Controlled Substances Certificate Registration - Grounds and Procedures Generally

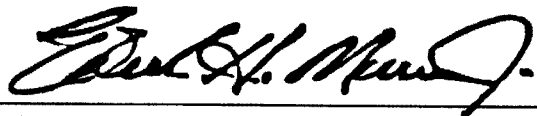
INTENDED ACTION: To amend the rule

SUBSTANCE OF PROPOSED ACTION: To amend the rule concerning assessment and claims for administrative costs

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: E. Wilson Hunter, General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including March 7, 2018. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Patricia E. Shaner, by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments. A copy of the proposal is available at the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: Friday, March 7, 2018

CONTACT PERSON AT AGENCY: E. Wilson Hunter, Esq.



Edward H. Munson, Jr., Acting Executive Director

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.

(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 ~~paid by the Board to outside counsel.~~
3. Travel expenses for Board staff.
4. Costs and expenses for documentary evidence.
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 ~~twenty-one (21)~~fourteen (14) days from ~~the close of evidence in the proceeding~~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)

History: Filed November 9, 1982 as Rule No. 540-X-3-.03. Readopted: Filed February 8, 1983. Amended: Filed March 23, 1984. Rules reorganized--rule number changed to 540-X-5-.03 (see conversion table at end of code): Filed June 14, 1984 (without publication in AAM). Amended: Filed May 16, 1985. Effective: June 20, 1985. Amended: Filed August 22, 1986. Amended: June 6, 2002. Effective Date: September 26, 2002. Amended/Approved: August 15, 2007. Emergency Rule Effective: September 4, 2007. Effective Date: December 17, 2007. Amended/Approved: January 17, 2018.