

APA-3  
Revised 1/2018

**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 15<sup>th</sup> day of December, 2022, and filed with the agency secretary on the 15<sup>th</sup> day of December, 2022.

AGENCY NAME: Alabama State Board of Medical Examiners

\_\_\_\_\_Amendment \_\_\_\_\_New \_\_\_\_\_X\_\_\_\_\_Repeal (Mark appropriate space)

Rule No. 540-X-4, Appendix A

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Application for Controlled Substances Registration Certificate

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

No comments received. No changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLI, ISSUE NO. 1, AAM,  
DATED OCTOBER 31, 2022.


Statutory Rulemaking Authority: Ala. Code §§ 20-2-1 et seq

(Date Filed)  
(For LRS Use Only)

REC'D & FILED

DEC 20 2022

LEGISLATIVE SVC AGENCY



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.

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AGENCY NAME: Alabama State Board of Medical Examiners

\_\_\_\_\_Amendment    \_\_\_\_\_New    \_\_\_\_X\_\_\_\_Repeal (Mark appropriate space)

Rule No. 540-X-4, Appendix B

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Alabama Controlled Substances Certificate Registration Renewal

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

No comments received. No changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLI, ISSUE NO. 1, AAM,  
DATED OCTOBER 31, 2022.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-1 et seq

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AGENCY NAME: Alabama State Board of Medical Examiners

\_\_\_\_\_Amendment    \_\_\_\_\_New    \_\_\_\_X\_\_\_\_Repeal (Mark appropriate space)

Rule No. 540-X-4, Appendix C

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Dispensing Physician Registration Form

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

No comments received. No changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLI, ISSUE NO. 1, AAM,  
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AGENCY NAME: Alabama State Board of Medical Examiners

  X   Amendment           New           Repeal (Mark appropriate space)

Rule No. 540-X-4-.02

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Application for an Alabama Controlled Substance Certificate

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

No comments received. No changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLI, ISSUE NO. 1, AAM,  
DATED OCTOBER 31, 2022.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-1 et seq

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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-.02 Application for an Alabama Controlled Substance 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.

(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 engaged in the excessive use of alcohol, controlled substances, or the use of illegal drugs, or receiving any therapy or treatment for alcohol or drug use, sexual boundary issues or mental health issues.

(a) If applicant is an anonymous participant in the Alabama Professionals Health Program and is in compliance with their assistance agreement, they may answer "No" to this question. Such answer for this purpose will not be deemed upon certification as providing false information to the Alabama Board of Medical Examiners.

(b) The term "currently" as it is used in paragraph (5) above does not mean on the day of, or even in the weeks or months preceding the completion of the



application. Rather, it means recently enough so that the condition referred to may have an ongoing impact on one's functioning as a physician within the last two years.

(c) Applicant shall initial certifying an understanding of a statement of the duty as a licensee to address any such condition, which states as follows:

IMPORTANT: The Board recognizes that licensees encounter health conditions, including those involving mental health and substance use disorders, just as their patients and other health care providers do. The Board expects its licensees to address their health concerns and ensure patient safety. Options include anonymously self-referring to the Alabama Professionals Health Program (334-954-2596), 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 Alabama 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/Approved October 20, 2022. Certified Rule Filed December 20, 2022. Effective Date February 13, 2023.

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AGENCY NAME: Alabama State Board of Medical Examiners

   X    Amendment               New               Repeal (Mark appropriate space)

Rule No. 540-X-4-.03

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Renewal of an 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:

No comments received. No changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLI, ISSUE NO. 1, AAM,  
DATED OCTOBER 31, 2022.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-1 et seq

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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-.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.
  - (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 engaged in the excessive use of alcohol, controlled substances, or the use of illegal drugs, or receiving any therapy or treatment for alcohol or drug use, sexual boundary issues or mental health issues.

1. If applicant is an anonymous participant in the Alabama Professionals Health Program and is in compliance with their assistance agreement, they may answer "No" to this question. Such answer for this purpose will not be deemed upon certification as providing false information to the Alabama Board of Medical Examiners.

2. The term "currently" as it is used in paragraph (5) above does not mean on the day of, or even in the weeks or months preceding the completion of the application. Rather, it means recently enough so that the condition referred to may have an ongoing impact on one's functioning as a physician within the last two years.

3. Applicant shall initial certifying an understanding of a statement of the duty as a licensee to address any such condition, which states as follows:

**IMPORTANT:** The Board recognizes that licensees encounter health conditions, including those involving mental health and substance use disorders, just as their patients and other health care providers do. The Board expects its licensees to address their health concerns and ensure patient safety. Options include anonymously self-referring to the Alabama Professionals Health Program (334-954-2596), 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.

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

**Author:** Alabama Board of Medical Examiners

**Statutory Authority:** Code of Alabama 1975, § 20-2-51; Act 2013-256 (amendment to § 20-2-214).

**History:** New rule approved September 18, 2013. Effective Date: December 19, 2013. Amended/Approved October 20, 2022. Certified Rule Filed December 20, 2022. Effective Date February 13, 2023.

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  X   Amendment           New           Repeal (Mark appropriate space)

Rule No. 540-X-4-.05

(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Registration of Dispensing Physicians

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

No comments received. No changes from proposal.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLI, ISSUE NO. 1, AAM,  
DATED OCTOBER 31, 2022.

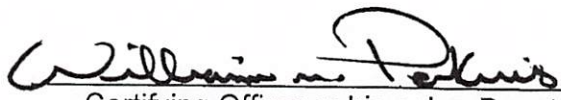
Statutory Rulemaking Authority: Ala. Code §§ 20-2-1 et seq

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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-.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 Ala. Code § 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 Ala. Code § 20-2-213 and regulations promulgated by the Alabama Department of Public Health pursuant to Ala. Code § 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/Approved for Publication: October 18, 2017.

**Effective Date:** January 29, 2018. Amended/Approved October 20, 2022.

**Certified Rule Filed December 20, 2022. Effective Date February 13, 2023.**