

ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODECHAPTER 540-X-12
QUALIFIED ALABAMA CONTROLLED
SUBSTANCES REGISTRATION CERTIFICATE (QACSC)

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540-X-12-.01 **Definitions.** The following definitions shall apply to the rules in this chapter:

(1) Administer - The direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient by any of the following:

(a) A supervising physician, or, in his or her presence, his or her authorized agent.

(b) An assistant to physician.

(c) The patient at the direction and in the presence of the supervising physician or assistant to physician.

(2) Assistant to Physician (P.A.) - Any person who is a graduate of an approved program, is licensed by the Board of Medical Examiners, and is registered by the Board to perform medical services under the supervision of a physician approved by the Board to supervise an assistant to physician.

(3) Board - The Board of Medical Examiners of the State of Alabama.

(4) Dispense - To deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a physician or Physician Assistant, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

(5) Excessive Dispensing - A registrant may be considered to have excessively dispensed a controlled substance if the Board finds that either the controlled substance was dispensed for no legitimate medical purpose, or that the amount of the controlled substance dispensed is not reasonably related to the proper medical management of the patient's illness or condition. Drug addiction shall not be considered an illness or condition which would justify the continued dispensing of a controlled substance, except in gradually decreasing dosages administered to the patient for the purpose of curing the addiction.

(6) Physician Supervision - A formal relationship between a licensed assistant to physician and a supervising physician under whom the assistant to physician is authorized to practice as evidenced by a written job description approved in accordance with Article 7, Chapter 24, Title 34, Code of Ala. 1975. Physician supervision requires that there shall be at all times a direct continuing and close supervisory relationship between the assistant to physician and the supervising physician to whom that assistant is registered. The term supervision does not require direct on-site supervision of the assistant to physician; however, it does require the professional oversight

and direction as may be required by the regulations and guidelines of the Board of Medical Examiners.

7. Prescribe or Prescribing - The act of issuing a prescription for a controlled substance.

(8) Prescription - Any order for a controlled substance written or signed or transmitted by word of mouth, telephone, telegraph, closed circuit television or other means of communication by a legally competent supervising physician or assistant to physician authorized by law to prescribe and administer such drug which is intended to be filled, compounded, or dispensed by a pharmacist.

(9) QACSC - Qualified Alabama Controlled Substances Registration Certificate.

(10) Supervising Physician - A doctor of medicine or a doctor of osteopathy licensed to practice medicine in Alabama who has been approved by the Board of Medical Examiners to supervise assistants to physicians and who holds a valid, current, and unrestricted Alabama Controlled Substances Registration Certificate.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: Filed January 20, 1988. **Amended:** Filed

March 19, 1992. **Repealed:** Filed May 20, 1996; effective

June 24, 1996. **New Rule:** Filed February 17, 2010; effective March 24, 2010.

540-X-12-.02 General Requirements.

(1) The Board is the certifying board which may issue to and renew, deny, restrict, limit, suspend, or revoke a QACSC of an assistant to physician.

(2) Beginning the calendar year 2010, QACSCs may be issued by the Board to Physician Assistants (P.A.s).

(3) Although the Board recognizes two categories of assistants to physicians, only a person licensed and registered by the Board as a Physician Assistant (P.A.) may be issued a QACSC.

(4) A P.A. who prescribes, administers, or authorizes for administration any controlled substance within Alabama or who proposes to engage in the prescribing, administering or authorizing for administration of any controlled substance within Alabama shall obtain, annually, a QACSC for each registration of the P.A. by the Board to perform medical services under the supervision of a physician.

(5) A P.A. who prescribes, administers, or authorizes for administration, or who proposes to engage in the prescribing, administering, or authorizing for administration of any controlled substance within Alabama shall obtain the appropriate registration or registrations issued by the United States Drug Enforcement Administration. A P.A. who applies for a Qualified 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 P.A. who is issued a Qualified Alabama Controlled Substances Certificate shall provide a copy of the DEA registration certificate to the Board immediately upon renewal of the registration.

(6) The Board of Medical Examiners may decline to consider an application when the P.A. or the supervising physician is under investigation for a potential violation of the Code of Ala 1975, Sections 20-2-50, et. seq., or 34-24-50, et. seq., or any rule of the Alabama Board of Medical Examiners or Medical Licensure Commission of Alabama.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: Filed January 20, 1988. **Repealed:** Filed May 20, 1996; effective June 24, 1996. **New Rule:** Filed February 17, 2010; effective March 24, 2010. **Amended:** Published August 31, 2022; effective October 15, 2022. **Amended:** Published December 30, 2022; effective February 13, 2023.

540-X-12-.03 **Requirements For The Issuance Of A Qualified Alabama Controlled Substances Registration Certificate (QACSC).**

To qualify for a QACSC, an individual must meet the following requirements:

(1) Be a Physician Assistant (P.A.) who holds a current and unrestricted license issued by the Board and who is registered by the Board to perform medical services under the supervision of a physician who holds and maintains a valid, current and unrestricted Alabama Controlled Substances Registration Certificate (ACSC);

(2) Be a P.A. who is practicing with appropriate physician supervision and in accordance with all statutes and rules governing P.A.s;

(3) Submit proof of successful completion of a course of courses (AMA PRA Category 1™) approved by the Board which includes eight (8) hours of instruction regarding the prescribing of controlled substances and four (4) hours of advanced pharmacology and prescribing trends relating to controlled substances within one (1) year preceding the filing of an application for a QACSC.

(4) Provide accurate and complete documentation of a minimum of twelve (12) months of active clinical practical pursuant to one or more registration agreements approved by the Alabama Board of Medical Examiners following National Commission on Certification of Physician Assistants (NCCPA) certification. Interim approval of a supervised practice shall not be considered or used to meet this requirement.

(5) Submit an application on forms provided by the Board.

(6) Provide information regarding whether the QACSC will be utilized at a remote site and/or in a different type of clinical setting than the supervising physician.

(7) Pay the required application fee required by the Board.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: Filed January 20, 1988. **Amended:** Filed March 19, 1992. **Repealed:** Filed May 20, 1996; effective June 24, 1996. **New Rule:** Filed February 17, 2010; effective March 24, 2010. **Amended:** Published February 28, 2020; effective April 13, 2020. **Amended:** Published December 30, 2022; effective February 13, 2023.

540-X-12-.03.01 Application For A Qualified Alabama Controlled Substances Registration Certificate (QACSC). An applicant for a Qualified Alabama Controlled Substances Certificate shall disclose whether:

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

(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, revoked, or disciplined in any manner for any reason related to the prescribing or administering 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 an assistant to physicians 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 Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Published December 30, 2022; effective February 13, 2023.

540-X-12-.04 Issuance Of A Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) The Board may issue a QACSC to a P.A. when all of the requirements for issuance have been met.

(2) Every QACSC issued shall have a unique QACSC number which identifies the particular applicant as a P.A. with a valid QACSC.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: Filed January 20, 1988. **Amended:** Filed March 19, 1992. **Repealed:** Filed May 20, 1996; effective June 24, 1996. **New Rule:** Filed February 17, 2010; effective March 24, 2010.

540-X-12-.04.01 Issuance Of An Additional Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) After the first QACSC for an approved registration has been obtained by a Physician Assistant pursuant to Board Rules 540-X-12-.02, .03 and .04, any subsequent QACSC

obtained for an additional registration shall be designated an additional QACSC.

(2) The Board may issue an additional QACSC to a Physician Assistant when all of the requirements for issuance have been met.

(3) Every additional QACSC issued shall have a unique QACSC number which identifies the particular applicant as a Physician Assistant with a valid QACSC.

(4) The fee for an additional QACSC is Sixty Dollars (\$60.00)

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama §20-2-69.

History: New Rule: Filed February 27, 2018; effective April 14, 2018.

540-X-12-.05 Renewal Of A Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) Renewal of a QACSC shall be annually on or before January 1st of each year. An application for annual renewal of a QACSC shall be received by the Board on or before December 31st and shall be accompanied by the required QACSC renewal fee.

(2) The Board shall not renew the QACSC of any P.A. when an administrative fine has been assessed by the Board until such fine is paid in full. In the event that the fine is subsequently reduced or set aside on judicial review, the P.A. shall be entitled to a prompt refund of the amount of the fine, but shall not be entitled to interest thereon.

(3) As a requirement for renewing a QACSC, a P.A. shall obtain, every two years, four (4) AMA PRA Category 1 credits™ or equivalent through a Board approved course or courses regarding the prescribing of controlled substances.

(4) Before renewing a Qualified 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.

(5) Before renewing a Qualified Alabama Controlled Substances Certificate, an applicant shall have a current and appropriate registration issued by the United States Drug Enforcement Administration.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §§20-2-60, et. seq.;
Act 2009-489.

History: **New Rule:** Filed February 17, 2010; effective March 24, 2010. **Amended:** Filed November 14, 2013; effective December 19, 2013. **Amended:** Filed March 19, 2015; effective April 23, 2015.

540-X-12-.05.01 Renewal Of A Qualified Alabama Controlled Substances Registration Certificate (QACSC) - Required Disclosures.

(1) 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, revoked, or disciplined in any manner in any state or U.S. territory.

(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 privileges at any hospitals have ever been suspended, restricted, revoked, or disciplined in any manner 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 an assistant to physicians 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 QACSC and/or license to practice as a Physician Assistant.
Author: Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §§20-2-60, et seq.
History: New Rule: Published December 30, 2022; effective February 13, 2023.

540-X-12-.06 Fees - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) An applicant for a QACSC shall submit to the Board an application fee in the amount of one hundred and ten dollars (\$110.00), 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.

(2) An applicant for annual renewal of a QACSC submitted on or before December 31 shall submit to the Board a QACSC renewal fee in the amount of Sixty Dollars (\$60.00), 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.

(3) An applicant for annual renewal of a QACSC submitted after the renewal deadline of December 31 and prior to January 31 shall submit to the Board a QACSC renewal fee in the amount of Sixty Dollars (\$60.00), 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, and a late fee in the amount of Seventy-Five Dollars (\$75.00).

(4) An applicant for annual renewal of a QACSC submitted after January 31 shall submit to the Board of QACSC renewal fee in the amount of Sixty Dollars (\$60.00) 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, and a penalty fee in the amount of One Hundred Ten Dollars (\$110.00).

(5) An applicant for annual renewal of a QACSC submitted after January 31 who has also prescribed controlled substances between January 1 and the date of application shall submit to the Board a QCSAS renewal fee in the amount of Sixty Dollars (\$60.00), 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, and a penalty fee in the amount of One Hundred Fifty Dollars (\$150.00).

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010. **Amended:** Published August 31, 2022; effective October 15, 2022.

540-X-12-.07 Utilization Of Qualified Alabama Controlled Substances Registration Certificate (QACSC) - Limitations.

(1) The authority of a P.A. to prescribe, administer, or authorize for administration pursuant to a QACSC is limited to those controlled substances enumerated in Schedules III, IV and V.

(2) A P.A. shall not prescribe, administer, or authorize for administration dispense any controlled substance enumerated in Schedule I or Schedule II.

(3) A P.A. shall prescribe, administer, or authorize for administration-controlled substances in accordance with the requirements of Code of Ala. 1975, §§0-2-60 through 20-2-69; any other applicable sections of the Alabama Uniform Controlled Substances Act (Code of Ala. 1975, §20-2-1, *et. seq.*); Board rules; protocols and medical regimens established by the Board for regulation of a QACSC; and any requirements or limitations established in an approved formulary by the supervising physician to whom the Physician Assistant is registered.

(4) A P.A. shall not utilize his or her QACSC for the purchasing, obtaining, maintaining or ordering of any stock supply or inventory of any controlled substance in any form.

(5) A P.A. who has been issued a valid and current QACSC may accept from pharmaceutical representatives prepackaged samples or starter packs in their original packages or containers for controlled substances enumerated in Schedules III, IV or V, subject to any restriction or limitations on the P.A.'s approved formulary and subject to any protocols or medical regimens established by the Board.

(6) A P.A. shall not prescribe, administer, or authorize for administration any controlled substance to his or her own self, spouse, child or parent.

(7) If the Alabama Controlled Substances Certificate of the supervising physician under whose supervision the P.A. utilizes a QACSC becomes inactive, revoked, suspended, restricted, or placed on probation, then the QACSC of the P.A. shall be administratively terminated by operation of law.

(8) When utilizing controlled substances for the treatment of pain, a QACSC holder shall comply with Ala. Admin. Code r. 540-X-4-.08, Requirements for the Use of Controlled Substances for the Treatment of Pain.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010. **Amended:** Published February 28, 2020; effective April 13, 2020. **Amended:** Published December 30, 2022; effective February 13, 2023.

Ed. Note: Certification contained a typo which indicated the rule number as .08 instead of .07 published February 28, 2020; effective April 13, 2020.

540-X-12-.07.01 Prescription Guidelines- Qualified Alabama Controlled Substances Registration Certificate (QACSC).

- (1) When prescribing controlled substances, a P.A. shall use a prescription form which includes all of the following:
 - (a) The name, medical practice site address and telephone number of the supervising physician.
 - (b) The name of the P.A.
 - (c) The medical practice site address and telephone number of the P.A. if different from that of the supervising physician.
 - (d) The P.A.'s license number.
 - (e) The words "Product Selection Permitted" printed on one side of the prescription form directly beneath a signature line.
 - (f) The words "Dispense as written" printed on one side of the prescription form directly beneath a signature line.
 - (g) The date that the prescription is issued to the patient.
 - (h) The patient's full name and address.
 - (i) The P.A.'s QACSC registration number.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Published December 30, 2022; effective February 13, 2023.

540-X-12-.08 Grounds For Denial And Discipline - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

The Board may deny a P.A.'s application for a QACSC, deny a P.A.'s application for renewal or reinstatement of a QACSC, or initiate disciplinary action against a P.A. possessing a QACSC based on the following grounds:

(1) Fraud or deceit in applying for, procuring, or attempting to procure a QACSC in the state of Alabama.

(2) Conviction of a crime under any state or federal law relating to any controlled substance.

(3) Conviction of a crime or offense which affects the ability of the P.A. to practice with due regard for the health or safety of his or her patients.

(4) Prescribing a drug or utilizing a QACSC in such a manner as to endanger the health of any person or patient of the P.A. or supervising physician.

(5) Suspension or revocation of a registration number issued to the P.A. by the United States Drug Enforcement Administration.

(6) Excessive dispensing or prescribing of a controlled substance to any person or patient of the P.A. or supervising physician.

(7) Unfitness or incompetence due to the use of or dependence on alcohol, chemicals, or any mood-altering drug to such an extent as to render the P.A. unsafe or unreliable to prescribe drugs or to hold a QACSC.

(8) Any violation of a requirement set forth in Code of Ala. 1975, §§20-2-60 through 20-2-69; a rule of the Board; a protocol or medical regimen adopted by the Board; or a limitation established by the supervising physician in an approved formulary.

(9) Prescribing a controlled substance without a valid QACSC.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010. **Amended:** Published August 31, 2022; effective October 15, 2022.

540-X-12-.09 Due Process Proceedings, Denial And Discipline - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) Before denying an application for a QACSC, denying an application for renewal or reinstatement of a QACSC or disciplining a P.A. possessing a QACSC, the Board shall serve upon the P.A. an order to show cause why registration should not be denied or disciplined.

(2) Any hearing concerning the order to show cause shall be before the Board.

(3) The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the Board at a time and place not less than thirty (30) days after the date of service of the order, but in the case of denial of renewal of registration, the show cause order shall be served not later than thirty (30) days before the expiration of the registration.

(4) Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(5) The Board may restrict, suspend or revoke a QACSC or assess an administrative fine against a QACSC whenever a P.A. shall be found guilty on the basis of substantial evidence of any of the acts or offenses enumerated in Rule 540-X-12-.08.

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

(7) The Board shall promptly notify the Drug Enforcement Administration of the United States Department of Justice of all orders suspending or revoking a QACSC.

(8) Any hearing before the Board shall be considered a contested case under the Alabama Administrative Procedure Act, Section 41-22-1, and shall be conducted in accordance with the requirements of that Act.

(9) In a hearing on the request for reinstatement of a QACSC, the Board has the authority to reinstate or deny reinstatement of a QACSC. In a hearing on a request for reinstatement of a QACSC, the applicant shall have the burden of establishing to the reasonable satisfaction of the Board that the applicant is entitled to the specific relief requested.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010. **Amended:** Published August 31, 2022; effective October 15, 2022.

540-X-12-.10 Conduct of Hearings - Qualified Alabama Controlled Substances Registration Certificate (QACSC). Except when Code of Ala. 1975, §§20-2-60 through 20-2-69 and Rule 540-X-12-.09 are in conflict and shall take precedence, hearings related to a QACSC are to be governed and conducted in accordance with Board Rules 540-X-6-.03 (Hearing Officer); 540-X-6-.04; and 540-X-6-.05.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010.

540-X-12-.11 Administrative Fines - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) In addition to the penalty of restricting, suspending or revoking a QACSC, the Board may assess an administrative fine not to exceed one thousand dollars (\$1,000.00) for each violation of any of the provisions of Code of Ala. 1975, §20-2-64, Rule 540-X-12-.08, or any Board rule governing the issuance, possession or utilization of a QACSC.

(2) All administrative fines levied by the Board shall be due and payable to the Board within thirty (30) days from the date the fine is levied.

(3) 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.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010.

540-X-12-.12 Administrative Costs - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) Administrative costs may be ordered by the Board in the following situations:

(a) A P.A. has been found by the Board to be in violation of any of the provisions of Code of Ala. 1975, §20-2-64 or Rule 540-X-12-.08.

(b) The application of a P.A. for a QACSC has been denied by the Board.

(c) The application of a P.A. for renewal of a QACSC has been denied by the Board.

(d) The application of a P.A. for reinstatement of a QACSC has been denied by the Board.

(2) Administrative costs are the actual costs, fees and expenses incurred by the Board in connection with any due process hearing concerning a QACSC or in connection with any investigation of the Board to determine eligibility of an applicant for a QACSC.

(3) Administrative costs include the following:

(a) Costs of independent medical review and expert testimony.

(b) Fees and expenses paid by the Board to outside counsel.

(c) Travel expenses for Board staff.

(d) Costs and expenses for documentary evidence.

(e) Deposition costs, court reporter fees and costs, and transcript costs.

- (f) Witness fees and expenses.
 - (g) Fees and costs for necessary interpreter services.
 - (h) Fees and expenses for necessary consultants.
- (4) 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) days from the close of evidence in the proceeding. Any ruling on administrative costs shall be made by the Board at the scheduled monthly meeting following submission of the bill of costs.
- (5) Payment of the administrative costs ordered by the Board shall be made and enforced in the same manner as an administrative fine stated in Rule 540-X-12-.11.
- Author:** Alabama Board of Medical Examiners
Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.
History: New Rule: Filed February 17, 2010; effective March 24, 2010.

540-X-12-.13 Appeals - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

- (1) A P.A. may obtain judicial review when adversely affected by any of the following:
- (a) An order of the Board denying an application for a QACSC.
 - (b) An order of the Board denying an application for renewal of a QACSC.
 - (c) An order of the Board suspending, revoking or restricting a QACSC or assessing an administrative fine against a QACSC.
 - (d) An order of the Board denying reinstatement of a QACSC.

(2) Judicial review of an order of the Board may be obtained by filing a written petition for review with the Circuit Court of Montgomery County in accordance with Code of Ala. 1975, §41-22-20.

(3) The following procedures shall take precedence over Code of Ala. 1975, §41-22-20(c) relating to the issuance of a stay of any order of the Board suspending, revoking or restricting a QACSC. The suspension, revocation or restriction of a QACSC shall be given immediate effect and no stay or supersedeas shall be granted pending judicial review of a decision by the Board to suspend, revoke or restrict a QACSC unless a reviewing court, upon proof by the party seeking judicial review, finds in writing that the action of the Board was taken without statutory authority, was arbitrary or capricious or constituted a gross abuse of discretion.

(4) From the judgment of the Circuit Court, either the Board or the affected party who invoked judicial review may obtain a review of any final judgment of the Circuit Court pursuant to Code of Ala. 1975, §41-22-21. No security shall be required of the Board.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010.

540-X-12-.14 Access To Records - Qualified Alabama Controlled Substances Registration Certificate (QACSC). The Board, its agents, attorneys, investigators, or inspectors shall be permitted access to inspect and copy any records of a P.A., including patient records, which relate to a request for a QACSC; a renewal of a QACSC; possible violations of any of the provisions of the Alabama Uniform Controlled Substances Act; possible violations of Code of Ala. 1975, §§20-2-60 through 20-2-69; or possible violations of any Board rule governing a QACSC.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010.

**540-X-12-.15 Covering Physician - Qualified Alabama
Controlled Substances Registration Certificate (QACSC).**

(1) A covering physician, as defined and designated in Board Rule 540-X-7-.24, who applies to supervise or does supervise a P.A. possessing a QACSC, shall hold a valid, current and unrestricted Alabama Controlled Substances Registration Certificate (ACSC).

(2) The covering physician shall state in writing to the Board the following:

(a) That he or she is familiar with the Board rules concerning the QACSC;

(b) That he or she is familiar with any protocols or medical regimens adopted by the Board concerning the QACSC;

(c) That he or she is familiar with any limitation on the prescribing of controlled substances agreed to in the approved formulary by the P.A. and the supervising physician to whom the P.A. is registered; and

(d) That, having full knowledge of the authority of the P.A. to prescribe controlled substances, he or she agrees to supervise the P.A. accordingly.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010.

540-X-12-.16 Controlled Substances Prescription Database

Access. All P.A.s possessing a QACSC who are permitted access to the information in the controlled substances database shall abide by the requirements and limitations stated in Code of Ala. 1975, §§20-2-210 through 20-2-220, where applicable.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, et. seq.; Act 2009-489.

History: New Rule: Filed February 17, 2010; effective March 24, 2010.

540-X-12-.18 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, practitioners 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, practitioners shall review that patient's prescribing history through the PDMP at least two (2) times per year, and each practitioner is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

(c) Practitioners 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 practitioners 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, practitioners should reconsider a patient's existing benzodiazepine prescriptions or decline to add one when prescribing an opioid and consider alternative forms of treatment.

(8) A violation of this rule is grounds for the assessment of a fine and for the suspension, restriction, or revocation of a practitioner's Alabama Controlled Substances Certificate or license to practice medicine.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §§20-2-60, et. seq.

History: New Rule: Filed June 24, 2019; effective August 8, 2019. **Amended:** Published February 26, 2021; effective April 12, 2021.

CHAPTER 540-X-12

APPENDIX A

ALABAMA BOARD OF MEDICAL EXAMINERS

(REPEALED 2/13/23)

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-60, 20-2-69.

History: New Rule: Filed February 17, 2010; effective March 24, 2010. **Amended:** Filed September 19, 2013; effective October 24, 2013. **Amended:** Filed February 27, 2018; effective April 14, 2018. **Amended:** Filed August 22, 2018; effective October 6, 2018. **Repealed:** Published December 30, 2022; effective February 13, 2023.

CHAPTER 540-X-12
APPENDIX B

QUALIFIED CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE FOR
PHYSICIAN ASSISTANTS RENEWAL
(REPEALED 2/13/23)

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §§20-2-50, 20-2-69.

History: New Rule: Filed February 17, 2010; effective March 24, 2010. **Amended:** Filed September 19, 2013; effective October 24, 2013. **Amended:** Filed November 14, 2013; effective December 19, 2013. **Amended:** Filed September 17, 2015; effective October 22, 2015. **Repealed and New Rule:** Filed July 20, 2017; effective September 3, 2017. **Amended:** Filed February 27, 2018; effective April 14, 2018. **Repealed:** Published December 30, 2022; effective February 13, 2023.

CHAPTER 540-X-12
APPENDIX C

APPLICATION FOR ADDITIONAL QUALIFIED CONTROLLED SUBSTANCES
REGISTRATION CERTIFICATE FOR PHYSICIAN ASSISTANT
(REPEALED 2/13/23)

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Ala. 1975, §20-2-69.

History: New Rule: Filed February 27, 2018; effective April 14, 2018. **Repealed and New Appendix:** Filed August 22, 2018; effective October 6, 2018. **Repealed:** Published December 30, 2022; effective February 13, 2023.