

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-18
QUALIFIED ALABAMA CONTROLLED
SUBSTANCES REGISTRATION CERTIFICATE (QACSC)
FOR CERTIFIED REGISTERED NURSE PRACTITIONERS (CRNP)
AND CERTIFIED NURSE MIDWIVES (CNM)

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540-X-18-.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 collaborating physician, or, in his or her presence, his or her authorized agent;

(b) A certified registered nurse practitioner (CRNP) or certified nurse midwife (CNM);

(c) The patient at the direction and in the presence of the collaborating physician, certified registered nurse practitioner (CRNP) or certified nurse midwife (CNM).

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

(3) Certified Nurse Midwife (CNM) - An advanced practice nurse who is subject to a collaborative practice agreement with a collaborating physician pursuant to § 34-21-5, Code of Alabama 1975, as amended, and who has advanced knowledge and skills relative to the management of women's health care focusing on pregnancy, childbirth, the postpartum period, care of the newborn, family planning, and gynecological needs of women, within a health care system that provides for consultation, collaborative management, or referral as indicated by the health status of the patient.

(4) Certified Registered Nurse Practitioner (CRNP) - An advanced practice nurse

who is subject to a collaborative practice agreement with a collaborating physician pursuant to § 34-21-5, Code of Alabama 1975, as amended, and who has demonstrated by certification that he or she has advanced knowledge and skills in the delivery of nursing services within a health care system that provides for consultation, collaborative management, or referral as indicated by the health status of the patient.

(5) Collaborating Physician - A doctor of medicine or a doctor of osteopathy licensed to practice medicine in Alabama who agrees in writing to practice in collaboration with one or more certified registered nurse practitioners or certified nurse midwives in accordance with § 34-21-5 and the rules and regulations adopted by the Alabama Board of Medical Examiners and the Alabama Board of Nursing.

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

(7) 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.

(8) Prescribe or Prescribing - The act of issuing a prescription for a controlled substance.

(9) 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 collaborating physician, certified registered nurse practitioner, or certified nurse midwife authorized by law to prescribe and administer the drug which is intended to be filled, compounded, or dispensed by a pharmacist.

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

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.02 General Requirements.

(1) The Board is the certifying board which may issue, renew, deny, restrict, limit, suspend, or revoke a QACSC for a CRNP or CNM.

(2) Beginning October 1, 2013, QACSCs may be issued by the Board to CRNPs and CNMs.

(3) A CRNP or CNM who prescribes, administers, authorizes for administration or dispenses any controlled substance within Alabama or who proposes to engage in the prescribing, administering, authorizing for administration or dispensing of any controlled substance within Alabama shall obtain, annually, a QACSC for each collaborative practice agreement approved by the Alabama Board of Nursing and the Alabama Board of Medical Examiners.

(4) A CRNP or CNM who prescribes, administers, authorizes for administration or dispenses, or who proposes to engage in the prescribing, administering, authorizing for administration or dispensing of any controlled substance within Alabama shall obtain the appropriate registration or registrations issued by the United States Drug Enforcement

Administration.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223.

History: Approved for publication: June 12, 2013.

540-X-18-.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 CRNP or CNM who is practicing in accordance with § 34-21-5, Code of Alabama 1975, as amended, and all Alabama Board of Nursing and Alabama Board of Medical Examiners rules governing collaboration between a qualified physician and a qualified CRNP or CNM and who is in a collaborative practice with a physician who holds a valid, current and unrestricted ACSC;

(2) Submit proof of successful completion of twelve (12) hours of AMA PRA Category 1 credits™ or the equivalent continuing medical education (CME), which shall include the following:

(a) “Prescribing Controlled Drugs; Critical Issues and Common Pitfalls,” a continuing medical education course jointly sponsored by the Board and the Medical Association of the State of Alabama (8 AMA PRA Category 1™ credits).

(b) Four (4) AMA PRA Category 1™ credits or equivalent through a Board approved course or courses that include advanced pharmacology and prescribing trends relating to controlled substances.

(3) Complete the required twelve (12) credits 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 practice pursuant to one or more collaborative practice agreements approved by the Alabama Board of Nursing and the Alabama Board of Medical Examiners. Temporary approval practice and provisional approval practice shall not be considered or used to meet this requirement.

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

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

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.04 Issuance of a Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) The Board may issue a QACSC to a CRNP or CNM 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 CRNP or CNM with a valid QACSC.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.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) As a requirement for renewing a QACSC, a CRNP or CNM shall obtain four (4) AMA PRA Category 1 credits™ or equivalent regarding the prescribing of controlled

substances every two years.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223.

History: Approved for publication: June 12, 2013.

540-X-18-.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 § 20-2-217, Code of Alabama 1975, as amended.

(2) An applicant for annual renewal of a QACSC 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 § 20-2-217, Code of Alabama 1975, as amended, .

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.07 Utilization of Qualified Alabama Controlled Substances Registration Certificate (QACSC) - Limitations.

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

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

(3) A CRNP or CNM shall prescribe, administer, authorize for administration or

dispense controlled substances in accordance with the requirements of §§ 20-2-250 through 20-2-259, Code of Alabama 1975, as amended; any other applicable sections of the Alabama Uniform Controlled Substances Act (§ 20-2-1, *et. seq.*, Code of Alabama 1975, as amended); Board rules; protocols, formularies, and medical regimens established by the Board for regulation of a QACSC; and any requirements or limitations established in an approved formulary by the collaborating physician.

(4) A CRNP or CNM 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 CRNP or CNM 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 CRNP's or CNM's approved formulary and subject to any protocols or medical regimens established by the Board.

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

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223.

History: Approved for publication: June 12, 2013.

540-X-18-.08 Grounds for Denial, Restriction, Limitation, Suspension or Revocation - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

The Board may deny a CRNP's or CNM's application for a QACSC, deny a CRNP's or CNM's application for renewal of a QACSC, or initiate action against the QACSC of a CRNP or CNM 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 CRNP or CNM 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 CRNP, CNM or collaborating physician.

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

(6) Excessive dispensing or prescribing of a controlled substance to any person or patient of the CRNP, CNM or collaborating 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 CRNP or CNM unsafe or unreliable to prescribe drugs or to hold a QACSC.

(8) Any violation of a requirement set forth in §§ 20-2-250 through 20-2-259, Code of Alabama 1975, as amended; a rule of the Board; a protocol or medical regimen adopted by the Board; or a limitation established by the collaborating physician in an approved formulary.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223.

History: Approved for publication: June 12, 2013.

540-X-18-.09 Due Process Proceedings - Denial of and Actions Against Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) Before denying an application for a QACSC, denying an application for renewal of a QACSC or taking action against a QACSC of a CRNP or CNM, the Board shall serve upon the CRNP or CNM an order to show cause why registration should not be denied or why the QACSC should not be restricted, limited, suspended or revoked.

(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 deny 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 whenever a CRNP or CNM shall be found guilty on the basis of substantial evidence of any of the acts or offenses enumerated in Rule 540-X-18-.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 restricting, limiting, suspending or revoking a QACSC.

(8) Any hearing before the Board shall be considered a contested case under the Alabama Administrative Procedure Act, § 41-22-1, et. seq., Code of Alabama 1975, as amended 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 Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.10 Conduct of Hearings - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

Except when §§ 20-2-250 through 20-2-259, Code of Alabama 1975, as amended, and Rule 540-X-18-.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 Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.11 Appeals - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) A CRNP or CNM 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;
- (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 § 41-22-20, Code of Alabama 1975, as amended.

(3) The following procedures shall take precedence over § 41-22-20(c), Code of Alabama 1975, as amended, 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 § 41-22-21, Code of Alabama 1975, as amended. No security shall be required of the Board.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.12 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 CRNP or CNM, 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 §§ 20-2-250 through 20-2-259, Code of Alabama 1975, as amended; or possible violations of any Board rule governing a QACSC.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.13 Covering Physician - Qualified Alabama Controlled Substances Registration Certificate (QACSC).

(1) A covering physician who applies to collaborate with or does collaborate with a CRNP or CNM 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 CRNP or CNM and the collaborating physician; and

(d) That, having full knowledge of the authority of the CRNP or CNM to prescribe controlled substances, the covering physician agrees to provide medical oversight for the CRNP or CNM accordingly.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

History: Approved for publication: June 12, 2013.

540-X-18-.14 Controlled Substances Prescription Database Access.

All CRNPs or CNMs possessing a QACSC who are permitted access to the

information in the controlled substances database shall abide by the requirements and limitations stated in §§ 20-2-210 through 20-2-220, Code of Alabama 1975, as amended, where applicable.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-250, *et. seq.*, Act 2013-223

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