

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 15th day of December, 2022, and filed with the agency secretary on the 15th day of December, 2022.

AGENCY NAME: Alabama State Board of Medical Examiners

_____Amendment _____New ____X____Repeal (Mark appropriate space)

Rule No. 540-X-12, Appendix A
(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Application for Qualified Controlled Substances Registration Certificate for Physician Assistant

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.

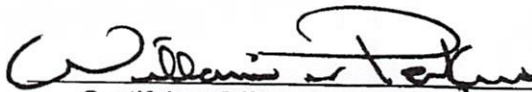
Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 et seq.

(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-12, Appendix B

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

Rule Title: Qualified Controlled Substances Registration Certificate for Physician Assistants 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 §§ 20-2-60 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-12, Appendix C
(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

Rule Title: Application for Additional Qualified Controlled Substances Registration
Certificate for Physician Assistant

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.

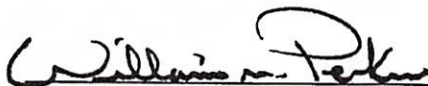
Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 et seq.

(Date Filed)
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AGENCY NAME: Alabama State Board of Medical Examiners

 X Amendment New Repeal (Mark appropriate space)

Rule No. 540-X-12-.02

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

Rule Title: General Requirements

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.

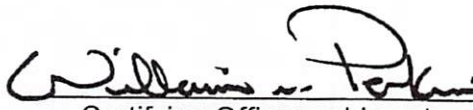
Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 et seq.

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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-12-.02 General Requirements.

(1) The Board is the certifying board which may issue or deny a QACSC to 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.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-60, *et. seq.*, Act 2009-489

History: Approved for publication: November 18, 2009. Effective Date: March 24, 2010. 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-12-.03

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

Rule Title: Requirements for the Issuance of a Qualified Alabama Controlled Substances Registration Certificate (QACSC)

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

No comments received. Numbering error in proposal was corrected for certified rule, and semicolons at end of paragraphs (1) and (2) changed to periods to match remaining rule.

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

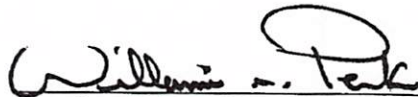
Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 et seq.

(Date Filed)
(For LRS Use Only)

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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-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 or 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 practice 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) 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.
- (6) Submit an application on forms provided by the Board.
- (7) Pay the required application fee required by the Board.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 20-2-60, *et. seq.*, Act 2009-489

History: Approved for publication: November 18, 2009. Effective Date: March 24, 2010. Amended/Approved: December 11, 2019. Certified Rule Filed: February 19, 2020. Effective Date: April 13, 2020. 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

_____Amendment X New _____Repeal (Mark appropriate space)

Rule No. 540-X-12-.03.01

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

Rule Title: Application for a Qualified Alabama Controlled Substances Registration Certificate (QACSC)

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 §§ 20-2-60 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.

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 Alabama § 20-2-60, *et. seq.*, Act 2009-489

History: New Rule 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

_____Amendment X New _____Repeal (Mark appropriate space)

Rule No. 540-X-12-.05.01

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

Rule Title: Renewal of a Qualified Alabama Controlled Substances Registration Certificate (QACSC) – Required Disclosures

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.

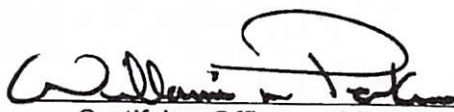
Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 et seq.

(Date Filed)
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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.

NEW

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 Alabama § 20-2-60, *et. seq.*

History: New Rule 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-12-.07

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

Rule Title: Utilization of Qualified Alabama Controlled Substances Registration Certificate (QACSC) - Limitations

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 §§ 20-2-60 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-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 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 Ala. Code §§ 20-2-60 through 20-2-69; any other applicable sections of the Alabama Uniform Controlled Substances Act (Ala. Code § 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 Alabama § 20-2-60, *et. seq.*, Act 2009-489

History: Approved for publication: November 18, 2009. Effective Date: March 24, 2010. Amended/Approved: December 11, 2019. Certified Rule Filed: February 19, 2020. Effective Date: April 13, 2020. Amended/Approved October 20, 2022. Certified Rule Filed December 20, 2022. Effective Date: 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.

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AGENCY NAME: Alabama State Board of Medical Examiners

_____Amendment X New _____Repeal (Mark appropriate space)

Rule No. 540-X-12-.07.01

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

Rule Title: Utilization of Qualified Alabama Controlled Substances Registration Certificate (QACSC) - Limitations

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

No comments received. Changes from proposal: semicolons after paragraphs (1)(b), (c), and (e) changed to periods.

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

Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 et seq.

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NEW

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 Alabama § 20-2-60, *et. seq.*, Act 2009-489

History: Amended/Approved October 20, 2022. Certified Rule Filed December 20, 2022. Effective Date February 13, 2023.