

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 19th day of June, 2019, and filed with the agency secretary on the 19th day of June, 2019.

AGENCY NAME: Alabama State Board of Medical Examiners

_____Amendment New _____Repeal (Mark appropriate space)

Rule No. **540-X-20-09**

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

Rule Title: **Risk and Abuse Mitigation Strategies**


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

Adopted without changes from the proposal. No comments were received.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXVII, ISSUE NO.7, AAM, DATED APRIL 30, 2019.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-50 through 57; 20-2-260; 34-24-53

(Date Filed)
(For LRS Use Only)



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.

REC'D & FILED

JUN 24 2019

LEGISLATIVE SVC AGENCY

540-X-20-.09 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) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) credits of *AMA PRA Category 1™* continuing medical education (CME) in controlled substance prescribing every two (2) years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

(9) 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 Alabama §§ 20-2-50, et. seq.; 20-2-260; 34-24-53

History: New Rule Approved for Publication: April 11, 2019. Certified Rule Filed June 24, 2019. Effective Date: August 8, 2019.

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 19th day of June, 2019, and filed with the agency secretary on the 19th day of June, 2019.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment New _____ Repeal (Mark appropriate space)

Rule No. **540-X-18-.15**

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

Rule Title: **Risk and Abuse Mitigation Strategies**

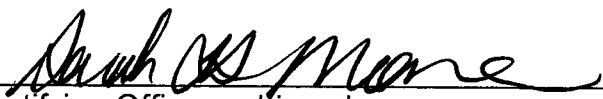
ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted without changes from the proposal. No comments were received.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXVII, ISSUE NO.7, AAM, DATED APRIL 30, 2019.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-250 through 259

(Date Filed)
(For LRS Use Only)



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.

REC'D & FILED

JUN 24 2019

LEGISLATIVE SVC AGENCY

540-X-18-.15 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) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) credits of *AMA PRA Category 1*[™] continuing medical education (CME) in controlled substance prescribing every two (2) years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

(9) 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: Ala. Code § 20-2-250, et. seq.

History: New Rule Approved for Publication: April 11, 2019. Certified Rule Filed June 24, 2019. Effective Date: August 8, 2019.

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 19th day of June, 2019, and filed with the agency secretary on the 19th day of June, 2019.

AGENCY NAME: Alabama State Board of Medical Examiners

_____Amendment ___X___New _____Repeal (Mark appropriate space)

Rule No. **540-X-12-18**

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

Rule Title: **Risk and Abuse Mitigation Strategies**

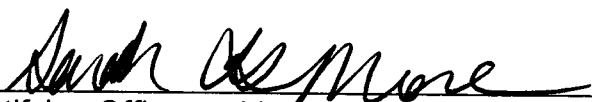
ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted without changes from the proposal. No comments were received.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXVII, ISSUE NO.7, AAM, DATED APRIL 30, 2019.

Statutory Rulemaking Authority: Ala. Code §§ 20-2-60 through 20-2-69

(Date Filed)
(For LRS Use Only)



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.

REC'D & FILED

JUN 24 2019

LEGISLATIVE SVC AGENCY

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) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) credits of *AMA PRA Category 1™* continuing medical education (CME) in controlled substance prescribing every two (2) years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

(9) 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: Ala. Code §§ 20-2-60, et. seq.

History: Approved for Publication: April 11, 2019. Certified Filed June 24, 2019. Effective Date: August 8, 2019.

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 19th day of June, 2019, and filed with the agency secretary on the 19th day of June, 2019.

AGENCY NAME: Alabama State Board of Medical Examiners

Amendment New Repeal (Mark appropriate space)

Rule No. **540-X-4-.09(1), new (2), (2)(f) and (g), new (4), (3)(a), (b), and (c), delete (7), (8)**

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

Rule Title: **Risk and Abuse Mitigation Strategies**

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

Adopted without changes from the proposal. Comments were received. See Public Notice pursuant to Ala. Code 41-22-5.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXVII, ISSUE NO.7, AAM, DATED APRIL 30, 2019.


Statutory Rulemaking Authority: Ala. Code §§ 34-24-53, 34-24-336, 20-2-54.1, and 20-2-214(2)

(Date Filed)
(For LRS Use Only)

REC'D & FILED

JUN 24 2019

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.

PUBLIC NOTICE

On June 19, 2019, the Alabama Board of Medical Examiners approved for final adoption, proposed rule 540-X-4-.09, Risk and Abuse Mitigation Strategies (“RMS”) by Prescribing Physicians. This rule will become effective on August 8, 2019. In compliance with Ala. Code § 41-22-5, the Alabama Board of Medical Examiners (“the Board”) states the following:

Exemption from requirement to query Prescription Drug Monitoring Database (PDMP) in certain cases (540-X-4-.09(6)).

The Board received comments urging the adoption of an additional exemption under 540-X-4-.09(6) for providers in the specialty of palliative medicine, to relieve them from the requirement to query the PDMP when prescriptions over certain morphine or lorazepam milligram equivalents are written.

The Board declined to adopt the exemption recommended by the comments, concluding that the regulatory burden placed on palliative care practitioners by the PDMP query requirement does not outweigh the benefit to the public health and safety associated with querying the PDMP, the purpose of which is to mitigate the risk of diversion, misuse, and abuse of controlled substances.

540-X-4-.09 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, physicians 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, physicians shall review that patient's prescribing history through the PDMP at least two (2) times per year, and each physician is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

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

(8) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) credits of *AMA PRA Category 1™* continuing medical education (CME) in controlled substance prescribing every two (2) years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

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

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-336, 20-2-54.1, and 20-2-214(2)

History: Approved for Publication: September 21, 2016. Adopted: January 18,

2017. Effective Date: March 9, 2017. Amended/Approved: May 16, 2018.
Certified approved: July 18, 2018. Certified filed: July 19, 2018. Effective Date:
September 4, 2018. Amended/Approved: April 11, 2019. Certified Rule Filed
June 24, 2019. Effective Date: August 8, 2019.