

APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-26-.04
Rule Title: Collaborative Drug Therapy Management Agreement: Required Terms

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? NO

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer William M. Perkins

Date: February 17, 2022

REC'D & FILED

FEB 17 2023

LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-26-.04, Collaborative Drug Therapy Management Agreement: Required Terms

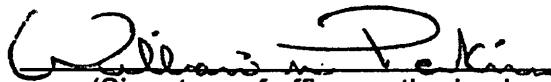
INTENDED ACTION: Amend the rule

SUBSTANCE OF PROPOSED ACTION: Amend to require that the renewal every two years of a Collaborative Drug Therapy Management Agreement shall occur by Dec. 31

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to Carla Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, PO Box 946, Montgomery, Alabama 36101-0946 or by email to bme@albme.gov until and including April 4, 2023. Persons wishing to submit data, views, or comments in person should contact the Board of Medical Examiners at bme@albme.gov or (334) 242-4116. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: April 4, 2023

CONTACT PERSON AT AGENCY: Carla H. Kruger



(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

540-X-26-.04 Collaborative Drug Therapy Management Agreement: Required Terms.

(1) Each Agreement shall contain the following elements, at a minimum:

(a) Names and Titles of Collaborating Providers. The Agreement must contain identification of the Collaborating Pharmacist, the Collaborating Physician, Covering Physician(s), and Covering Pharmacist(s) who are parties ("collaborating providers") to the Agreement. The Agreement shall state the procedure to be followed to indicate changes in the collaborating providers participating in the Agreement. Unless expressly stated in the Agreement, changes to the list of collaborating providers bound by the Agreement shall not automatically void the Agreement. Signatures may be handwritten, electronic, or any other method authorized by the Board of Pharmacy and the Board of Medical Examiners.

(b) Authorized Care and Services. The Agreement must contain an "Authorized Care and Services" section defining the nature and scope of patient care services and activities, including screening, prevention, assessment, management, and care, authorized or restricted, to be provided by the Collaborating Pharmacist pursuant to approved Protocol(s) under the Agreement. All care and services to be provided shall be within the routine scope of practice and services delivered by the Collaborating Physician; provided, however, that the authorized care and services may not be broader in scope than the permissible functions and activities authorized under the Collaborating Pharmacist's license, training, experience, and Board of Pharmacy's laws, rules, policies, and procedures. All care and services provided, with the exception of immunizations, opioid antagonists, and screening or testing which do not require such patient-specific plans, must be pursuant to a diagnosis appropriately made and documented by the

Collaborating Physician. An Agreement which includes a Protocol authorizing the Collaborating Pharmacist to modify or discontinue drug therapy must include specific authorization in the authorized care and services portion of the Agreement and must contain a Formulary that may be modified or discontinued by the Collaborating Pharmacist under the terms of the Agreement.

(c) Documentation and Communication. The Collaborating Physician shall be responsible for documenting the communication in the patient medical record maintained by the Collaborating Physician. The Collaborating Physician shall, within 24 hours, communicate to the Collaborating Pharmacist any changes initiated to a patient's drug therapy that is subject to an Agreement; a written, telephonic, or electronic prescription which contains specific dosage information may satisfy this requirement. The collaborating pharmacist shall, within 24 hours, communicate to the collaborating physician any changes to a patient's drug therapy and/or individual patient care services as set out in the Agreement. The Agreement shall describe the methods for documenting the patient medical record by the Collaborating Pharmacist and the Collaborating Physician, for documentation of services performed pursuant to the Agreement, and for communication and feedback between the Collaborating Pharmacist and the Collaborating Physician. All such records shall be maintained by the Collaborating Physician for a period of not less than six (6) years from the date of the last patient contact, or if the patient is a minor, the record shall be maintained for a period of not less than eight (8) years from the date of the last patient contact. All such records shall be maintained by the Collaborating Pharmacist within the employing pharmacy for a period of not less than two (2) years from the date of the last patient contact.

(d) **Override Clause.** A provision must be included in the Agreement providing for the Collaborating Physician to override the actions taken by the Collaborating Pharmacist specific to services provided under the Agreement. This provision must state how such overrides shall be documented and communicated to the Collaborating Pharmacist and the patient in a timely manner, as defined in the Agreement.

(e) **Expiration, Modification, and Termination.** The effective date of the Agreement shall be stated in the Agreement. Each Agreement must contain a term or expiration date upon which the Agreement will expire if not renewed; however, in any event, all Agreements must be reviewed, updated where applicable, and renewed by December 31 at least every two (2) years as evidenced by signatures of the parties. Every Agreement must contain a provision stating the process for modification or termination of the Agreement by any of the parties. An Agreement may be amended upon mutual approval by the Collaborating Physician and Collaborating Pharmacist who have been duly authorized to execute, modify, or change the Agreement. Such amendments shall include, at a minimum, a description of the desired change and the effective date of the change. Any amendment executed shall not automatically void the terms and conditions of the existing Agreement unless expressly stated. Amendments to the authorized care and services which establish substantive additions or reductions to the scope of patient care services provided under the Agreement, including new therapeutic classes of drugs added to the authorized Formulary, must be provided to the Board of Pharmacy and Board of Medical Examiners no later than ten (10) days from the date the amendment is signed by the parties.

(f) **Automatic Exclusions.** Agreements must have a provision that identifies any terms under which a provider will be automatically excluded from participation in the Agreement, which shall include, but are not limited to: death; the suspension, surrender, revocation, or retirement of license; loss or restriction of prescriptive authority; the suspension, surrender, or revocation of a Drug Enforcement Administration registration or Alabama Controlled Substances Certificate; or exclusion from any federally-funded health programs.

(g) **Quality Assurance.** The Collaborating Physician and Collaborating Pharmacist shall engage in a quality assurance review of the care provided for patients pursuant to the Agreement on a quarterly basis. Quality Assurance shall include, and the Agreement shall provide for, a quarterly review by the Collaborating Physician of a meaningful sample of patient records. A “meaningful sample” shall consist of:

1. Not less than twenty-five percent (25%) of the patients treated pursuant to the Agreement for the first two years of the Agreement;
2. Not less than ten percent (10%) of the patients treated pursuant to the Agreement after the Agreement has been in effect for two years; and
3. All adverse outcomes of the patients treated pursuant to the Agreement.

The quality assurance review shall be properly documented, retained by the participating parties of the Agreement, and available for review by representatives of the Board of Medical Examiners for at least five (5) years and the Board of Pharmacy for at least two (2) years.

(h) **All Agreements shall require the Collaborating Pharmacist to use an area for in-person or other approved consultations with patients that ensures the confidentiality**

of the communication and complies with the requirements and standards set forth by the Board of Pharmacy in ALA. ADMIN. CODE r. 680-X-2-.27.

(i) Notice. All Agreements shall include a provision stating which party or parties shall bear the costs and responsibility of promptly notifying affected individuals in the event that an Agreement expires or is terminated. All Agreements shall specify when patients served by an Agreement are to be notified of changes to the Agreement. Any provision of the Agreement notwithstanding, the patients served by an Agreement shall be promptly notified when a Collaborating Physician or Collaborating Pharmacist departs from or is terminated from an Agreement, and said notice shall include the Collaborating Physician's or Collaborating Pharmacist's contact information as well as instructions for how patients may obtain copies of their records or have them forwarded to the physician or pharmacist of their choice.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code § 34-24-53; Act 2019-368 (Ala. Code § 34-23-77)

History: Approved for publication: April 15, 2021. Certified Rule Filed August 20, 2021. Effective Date: October 15, 2021. Amended/Approved for Publication February 16, 2023.

APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-26-.08
Rule Title: Approval of the Collaborative Drug Therapy Management Agreement

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

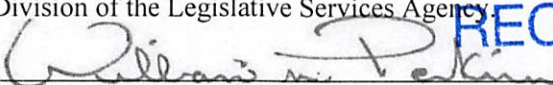
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Does the proposed rule have an economic impact? NO

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Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer  **REC'D & FILED**

Date: February 17, 2022 **FEB 17 2023**

LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-26-.08, Approval of the Collaborative Drug Therapy Management Agreement

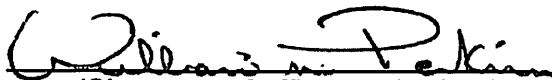
INTENDED ACTION: Amend the rule

SUBSTANCE OF PROPOSED ACTION: Amend to require that the renewal every two years of a Collaborative Drug Therapy Management Agreement shall occur by Dec. 31

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to Carla Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, PO Box 946, Montgomery, Alabama 36101-0946 or by email to bme@albme.gov until and including April 4, 2023. Persons wishing to submit data, views, or comments in person should contact the Board of Medical Examiners at bme@albme.gov or (334) 242-4116. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: April 4, 2023

CONTACT PERSON AT AGENCY: Carla H. Kruger



(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

540-X-26-.08 Approval of the Collaborative Drug Therapy Management Agreement.

(1) A physician and pharmacist shall not engage in Collaborative Drug Therapy Management until the Agreement is approved by both the Board of Medical Examiners and the Board of Pharmacy.

(2) Agreements must be submitted to the Board of Medical Examiners and the Board of Pharmacy within ten (10) days after the Agreement is signed by all parties.

(3) Any amendment or addendum to an Agreement must be submitted to the Board of Medical Examiners and Board of Pharmacy within ten (10) days after the amendment is signed by all parties.

(4) No Agreement, nor any amendment or addendum thereto, shall be effective until it is approved by both the Board of Pharmacy and the Board of Medical Examiners.

(5) Each Agreement submitted to the Board of Medical Examiners shall be accompanied by a fee of three hundred dollars (\$300), except those Agreements submitted by a physician who is engaging in Collaborative Drug Therapy Management at an indigent clinic, in which case the fee may be \$1. Each application requesting the nominal fee will be placed before the Joint Committee for individual review. This fee is due and payable concurrently with the submission of an application for a Collaborative Drug Therapy Management Agreement. The fee is not refundable.

(6) Each Agreement submitted to the Board of Pharmacy shall be accompanied by a fee of one hundred dollars (\$100), except those Agreements submitted by a pharmacist who is engaging in Collaborative Drug Therapy Management at an indigent

clinic, in which case the fee may be \$1. Each application requesting the nominal fee will be placed before the Joint Committee for individual review. This fee is due and payable concurrently with the submission of an application for a Collaborative Drug Therapy Management Agreement. The fee is not refundable.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code § 34-24-53; Act 2019-368 (Ala. Code § 34-23-77)

History: Approved for publication: April 15, 2021. Certified Rule Filed August 20, 2021. Effective Date: October 15, 2021. Amended/Approved for Publication February 16, 2023.

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TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-26-.12
Rule Title: Renewal

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

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Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? NO

Does the proposed rule have an economic impact? NO

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Certification of Authorized Official

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Signature of certifying officer William P. Perkins **REC'D & FILED** **FEB 17 2023**

Date: February 17, 2022 **LEGISLATIVE SVC AGENCY**

APA-2

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-26-.12, Renewal

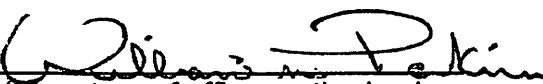
INTENDED ACTION: Amend the rule

SUBSTANCE OF PROPOSED ACTION: Amend to require that the renewal every two years of a Collaborative Drug Therapy Management Agreement shall occur by Dec. 31

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FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: April 4, 2023

CONTACT PERSON AT AGENCY: Carla H. Kruger


(Signature of officer authorized
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540-X-26-.12 Renewal.

(1) Agreements shall be renewed by December 31 every two (2) years.

(2) Each Collaborating Physician and Collaborating Pharmacist renewing an Agreement shall review the terms, conditions, protocols, parties, and content of the Agreement and shall certify that the information is accurate and complies with this Chapter.

(3) The fee for renewing an Agreement with the Board of Medical Examiners shall be two hundred dollars (\$200).

(4) The fee for renewing an Agreement with the Board of Pharmacy shall be fifty dollars (\$50).

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code § 34-24-53; Act 2019-368 (Ala. Code § 34-23-77)

History: Approved for publication: April 15, 2021. Certified Rule Filed August 20, 2021. Effective Date: October 15, 2021. Amended/Approved for Publication February 16, 2023.