TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control  540  Department or Agency  Alabama State Board of Medical Examiners
Rule No.  540-X-26
Rule Title:  Collaborative Pharmacy Practice
  X  New  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 ..............

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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.

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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  (Signature)  William M. Perkins, Executive Director

Date  September 21, 2020
ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-26, Collaborative Pharmacy Practice

INTENDED ACTION: Add a new chapter of rules


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 H. Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including November 4, 2020. Persons wishing to obtain copies of the text of this rule should contact Carla H. Kruger by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments. Copies can also be obtained at the Board’s web site, www.albme.org.

A public hearing to receive oral comments is scheduled on Monday, November 2, 2020, at 2:00 p.m., CST, at the offices of the Alabama Board of Medical Examiners, 848 Washington Avenue, Montgomery, Alabama.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: November 4, 2020

CONTACT PERSON AT AGENCY: Carla H. Kruger

William M. Perkins
Executive Director
540-X-26-.01 Definitions

1. The following definitions are applicable to collaborative drug therapy management:

   a) “Agreement” means the Collaborative Drug Therapy Management Agreement.

   b) “Board of Medical Examiners” means the State Board of Medical Examiners established pursuant to Ala. Code § 34-24-53.

   c) “Board of Pharmacy” means the State Board of Pharmacy established pursuant to Ala. Code § 34-23-90.
(d) "Collaborative Drug Therapy Management" means the practice of pharmacy whereby an individual pharmacist licensed in this state jointly and voluntarily works with an individual physician licensed in this state under a Collaborative Drug Therapy Management Agreement to provide a range of services to a patient of the physician intended to optimize therapeutic outcomes, detect and prevent adverse medication interactions and side effects, provide education on the patient's medications used to treat the disease state, ensure that medications are taken correctly, monitor, modify, and discontinue drug therapy as directed by the physician, provide education on managing medication side effects, and communicate with third party payors and insurers regarding prior authorization for prescription medications.

(e) "Collaborating Physician" means a physician who is a party to a Collaborative Drug Therapy Management Agreement, who has a direct physician-patient relationship with the patient served by the Agreement, and who has prepared the patient-specific, drug-specific, disease-specific, or condition-specific plan of care based on a physical examination of the patient where required under this Chapter.

(f) "Formulary" means a list of drugs that may be utilized under a Collaborative Drug Therapy Management agreement.

(g) "Hospice Patient" means an individual who has voluntarily requested admission to, and been accepted by, a licensed hospice as defined by the Alabama Department of Public Health.

(h) "Institutional-based Pharmacy Setting" means any institutional facility, hospital, or long-term care facility, as each is defined by the Alabama Department of
Public Health, where the pharmacist is responsible for the care of patients within that facility under the terms of a Collaborative Drug Therapy Management Agreement.

(i) "Patient Care Services" means services rendered by physicians, advanced practice nurses, physician assistants, and pharmacists for the benefit of the patient and which must be within the professional training and experience of the healthcare provider and be covered by the Collaborative Drug Therapy Management Agreement.

(j) "Protocol" means a document approved by the Board of Medical Examiners and Board of Pharmacy establishing the permissible functions and activities to be performed by pharmacists and signed by the parties to the Collaborative Drug Therapy Management Agreement.

(k) "Quality Assurance" means documented evaluation by the Collaborating Physician of the clinical practice of the collaborating pharmacist(s) against defined quality outcome measures, using a selected, meaningful sample of patient records, as defined in this Chapter, which will identify areas needing improvement, set performance goals, and assess progress towards meeting established goals, with a summary of findings, conclusions, and, if indicated, recommendations for change. The physician's signature on the patient record does not constitute quality assurance monitoring.

(l) "Routine Scope of Practice and Services" means any patient care service provided by the collaborating physician and his or her practice in compliance with his or her medical education, training, and experience and with the Board of Medical Examiners’ laws, rules, policies and procedures. In addition, the services to be provided by the pharmacist(s) shall be services that the collaborating physician(s) generally provides to his or her patients in the normal course of his or her clinical medical practice.
(m) "Unrestricted," for the purpose of this rule, means an active license that is not revoked, suspended, or on probation at the time and is not subject to any conditions, restrictions, or limitations imposed by the applicable licensing board, which relate directly to the delivery of health care services. A condition, restriction, or limitation directly relates to the delivery of health care services when it prevents a provider from treating certain types of patients or certain types of ailments or injuries, or otherwise limits a provider from fully engaging in the practice which would otherwise be authorized pursuant to his or her license.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 16, 2020.

540-X-26-.02 Collaborative Drug Therapy Management Agreement Required

(1) Physicians may only engage in Collaborative Drug Therapy Management with pharmacists when:

(a) an Agreement has been appropriately executed and a written attestation has been filed with and approved by the Board of Pharmacy and the Board of Medical Examiners; and

(b) the patient or the patient's authorized representative has signed an Agreement-specific consent that the patient is to receive services from a healthcare team, including a pharmacist. However, no such consent shall be required in an institutional based pharmacy setting where general consent to treatment has already been given.
(2) The patient’s consent to treatment at an institutional facility or to treatment under a Collaborative Drug Therapy Management Agreement shall be made part of the patient record.

(3) The written attestation shall include the names of all signatories and providers participating in the Agreement, the date of the Agreement, and a description of the scope of the services covered by the Agreement.

(4) For those Agreements not involving the institutional-based pharmacy setting, the written attestation shall include a formulary of the categories of drugs and services authorized by the Agreement.

(5) The Agreement and written attestation must be provided to the Board of Pharmacy and the Board of Medical Examiners no later than ten (10) days after the Agreement is signed by the parties.

(6) A copy of the Agreement, including any addendum, modification, or termination shall be accessible at each practice site and shall be made available to the Board of Pharmacy and Board of Medical Examiners for review upon request.

Author: Alabama Board of Medical Examiners


History: Approved for publication: September 16, 2020.

540-X-26-.03 Eligibility Requirements

(1) No physician may engage in a Collaborative Drug Therapy Management Agreement unless each collaborating physician and pharmacist who is a party to the Agreement holds an active, unrestricted license in Alabama and possesses at least one million dollars ($1,000,000) in professional liability insurance coverage per occurrence.
(2) No physician may enter into an Agreement with a collaborating pharmacist who is not licensed by the Board of Pharmacy, does not have an active, unrestricted license, and does not comply with each term and requirement of the Board of Pharmacy’s rule(s) regarding Collaborative Drug Therapy Management.

(3) A physician engaged in an Agreement with a pharmacist shall have:

(a) An active, unrestricted license to practice medicine in the State of Alabama;

(b) Practiced medicine for at least three years, or have practiced medicine for at least one year, if the physician is certified by a specialty board approved by the American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS); and

(c) Paid all collaborative practice fees due to the Board of Medical Examiners.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 16, 2020.

540-X-26-.04 Collaborative Pharmacy 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 all pharmacists and all physicians 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. When the Agreement involves a group or groups of providers, the chief medical officer or medical director,
where applicable, and the director of pharmacy or pharmacist-in-charge shall sign the Agreement, and the Agreement shall identify all collaborating providers in one or more addendums. In the case of a healthcare institution with an organized medical staff or a multi-specialty group with more than one American Board of Medical Specialties (ABMS) or American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS) recognized physician specialty, the signature of the collaborating physician representing or responsible for that specialty unit will suffice. Nevertheless, each collaborating provider must (1) satisfy the eligibility requirements; (2) pay all fees; and (3) affirm his or her understanding and acceptance of the terms of the Agreement by signing an addendum to the Agreement within ten (10) days of the effective date of the Agreement (or within ten (10) days of employment or association with such multi-specialty group) and all members of the medical staff or group must be provided a copy of the collaborative Agreement within ten (10) days of execution, with a copy also made available via online access. 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 a provision 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 pharmacist(s) under the Agreement. All care and services authorized to be provided shall be within the routine scope of practice and services delivered by the collaborating physician(s). All care and services provided, except immunizations and opioid antagonists, must be pursuant to a diagnosis appropriately made and documented by the collaborating physician(s). An Agreement which grants the collaborating
pharmacist(s) authority 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 listing the categories of drugs that may be modified or discontinued by the collaborating pharmacist(s) under the terms of the Agreement.

(c) Documentation and Communication. The collaborating physician shall receive notification of any patient care services provided by a collaborating pharmacist(s) pursuant to an Agreement on the same day that the service is rendered. The collaborating physician shall be responsible for documenting the communication in the patient medical record maintained by the collaborating physician. The Agreement shall describe the methods for documenting the patient medical record by the pharmacist(s) and the physician(s), for documentation of services performed pursuant to the Agreement, and for communication and feedback between the pharmacist(s) and the collaborating physician(s). All such records shall be maintained by the collaborating physician(s) for a period of not less than five (5) 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(s) to override the actions taken by the collaborating pharmacist(s) specific to services provided under the Agreement. This provision must state how such overrides shall be documented and communicated to the collaborating pharmacist(s) 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 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, as well as a provision stating which party or parties shall bear the costs of notification. This process shall include written notification to all affected parties when modification or termination is sought. An Agreement may be amended upon mutual approval by the collaborating physician(s) and pharmacist(s) 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. Additional prescriber(s) and additional pharmacist(s) may be added to an existing participating group through an addendum without affecting the effective date of the Agreement. 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 not involving an institutional-based pharmacy setting 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(s) and pharmacist(s) shall create written measurable and objective performance goals for evaluating the quality of care provided for the patients treated pursuant to the Agreement. The Agreement must provide for such goals and data as identified by the collaborating physician(s), to be aggregated and reviewed by the participants to the Agreement at least quarterly. Such quarterly review shall include consideration of any changes necessary to the Agreement, authorized formulary, and patient orders, in addition to strategies regarding patient education and medication adherence, increased or improved monitoring of side effects, and the need for further screening/testing. The Agreement shall also provide for, at a minimum, monthly patient record review by the collaborating physician(s) of at least thirty-five per cent (35%) 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 Pharmacy and the Board of Medical Examiners for at least five (5) years.

(h) All Agreements authorizing pharmacists to provide services and activities within an institutional-based pharmacy setting shall include language that ensures compliance with all applicable by-laws, policies, and procedures of that facility.

(i) All Agreements authorizing pharmacists to provide services and activities shall require the use of and include a description of the area to be used by the pharmacist(s) for in-person, telephonic, or other approved consultations with patients that ensures the confidentiality of the communication.
Limitations

(1) The scope of an Agreement shall NOT include:

(a) Any person or patient of a collaborating physician for whom such collaborating physician has not prepared a patient-specific, drug-specific, disease-specific, or condition-specific plan of care based on a physical examination of the patient by the collaborating physician within the past twelve (12) months, with the exception of immunizations and screening or testing which do not require such patient-specific plans, as well as the dispensing of opioid antagonists as defined in Ala. Code § 20-2-280 which does not require a physical examination or a patient-specific plan; or

(b) The prescribing of controlled substances listed or to be listed in the schedules under federal law and in Ala. Code §§ 20-2-23, 20-2-25, 20-2-27, 20-2-29, and 20-2-31 and/or ALA. ADMIN CODE r. 420-7-2 and its Appendix.

(2) No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement. Nothing shall prohibit a retail pharmacy from hiring a physician or licensed medical practitioner for the purpose of conducting quality assurance reviews of its pharmacists that are engaged in the practice of collaborative drug therapy.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 16, 2020.

540-X-26-.05 Limitations

540-X-26-.06 Standards for Physicians
(1) Physicians engaged in an Agreement shall:

(a) Retain professional responsibility to his or her patients for the management of their drug therapy;

(b) Provide professional medical oversight and direction to the collaborating pharmacist(s);

(c) Establish and maintain a physician-patient relationship with each patient receiving services under the Agreement;

(d) Be available at all times through direct telecommunication for consultation, assistance, and direction, or shall make arrangements for a substitute physician who is pre-approved by the Board of Medical Examiners and is familiar with these rules to be available.

(2) In the event of an unanticipated, permanent absence of a collaborating physician, a previously approved substitute physician may be designated as a temporary collaborating physician for a period of up to sixty (60) days. During the sixty (60) day time period, a new Agreement designating a new collaborating physician should be submitted for approval.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 16, 2020.

540-X-26-.07 Approval of the Collaborative Drug Therapy Management Agreement

(1) A physician shall not engage in Collaborative Drug Therapy Management until the Agreement is approved by the Board of Medical Examiners.
(2) Agreements must be submitted to the Board of Medical Examiners 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 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 physician entering into an Agreement shall pay a fee to the Board of Medical Examiners of three hundred dollars ($300). This fee is required for each Agreement in which a physician is a party. This fee is due and payable concurrently with the submission of an application for a Collaborative Drug Therapy Management Agreement.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 16, 2020.

540-X-26-.08 Denial, Modification, Restriction, or Termination of a Collaborative Drug Therapy Management Agreement

(1) The Board of Medical Examiners may deny approval of any Agreement based on any of the grounds specified in this Chapter. A physician whose Agreement is denied approval by the Board of Medical Examiners may petition the Board of Medical Examiners for reconsideration of the application. Any petition must be filed within thirty (30) days of the denial. The failure to petition for reconsideration within the timeframe
specified within the notice of denial shall be deemed a waiver. Upon receipt of the petition, the Board shall approve the Agreement or set a hearing. The hearing shall be considered a contested case and shall be conducted in accordance with Ala. Code § 41-22-1, *et seq.*, and ALA. ADMIN CODE r. 540-X-6-.02(1)(b)(3).

(2) The Board of Medical Examiners on its own motion may investigate any evidence which appears to show that a collaborating physician is or may be guilty of a violation of any of the acts, offenses, or conditions set out in this Chapter. A violation of this Chapter is grounds for disciplinary action and sanctions against a collaborating physician and shall be prosecuted against and in the name of the collaborating physician or physicians participating in the alleged violation.

(3) A violation of this Chapter may be punished by termination, modification, or restriction of the collaborating physician’s Agreement, a fine of up to ten thousand dollars ($10,000) per violation, the filing of formal charges against the physician’s medical license under Ala. Code § 34-24-360, or any combination thereof.

(4) Before modifying, restricting, or terminating an Agreement on any of the grounds specified in this Chapter, the Board shall conduct a hearing under the provisions of the Alabama Administrative Procedure Act, Ala. Code §§ 41-22-1 through 41-22-27, and ALA. ADMIN CODE 540-X-6.

(5) Pursuant to the requirements Ala. Code § 41-22-19(d), the Board may order the summary suspension of the Board’s approval of an Agreement for any of the reasons stated in this Chapter if the Board finds that danger to the public health, safety, or welfare necessitates the emergency suspension of an Agreement.
(6) An order of summary suspension of the Board's approval of an Agreement shall become effective immediately, unless otherwise stated in the order. Simultaneously with the issuance of an order of summary suspension, a proceeding for a hearing shall be instituted. The suspension may be effective for a period of not longer than one hundred and twenty (120) days.

(7) If the Alabama medical license of a collaborating physician becomes inactive, revoked, suspended, restricted, or placed on probation, then that physician's participation in any and all Agreements shall be administratively terminated by operation of law.

Author: Alabama Board of Medical Examiners


History: Approved for publication: September 16, 2020.

540-X-26-.09 Grounds for Denial, Modification, Restriction, or Termination of a Collaborative Drug Therapy Management Agreement

(1) The following acts shall constitute grounds for the denial of approval or the termination of an Agreement:

(a) Failure of a physician to comply with any term or requirement of this Chapter or the terms of the Agreement;

(b) A finding by the Board of Medical Examiners that an Agreement contains false, misleading, or untruthful information, or that a physician has submitted or caused to be submitted false, misleading, or untruthful information to the Board of Medical Examiners in connection with a Collaborative Drug Therapy Management Agreement;
(c) A finding by the Board of Medical Examiners that a physician has committed any of the acts or offenses constituting grounds to discipline the license to practice medicine in this state pursuant to Ala. Code § 34-24-360;

(d) A finding by the Board of Medical Examiners that a physician has committed any of the acts or offenses constituting grounds to discipline the controlled substances registration of the physician under Ala. Code § 20-2-54;

(e) A finding by the Board that a party to the Agreement is under any state or federal restriction, probation, discipline, investigation, or indictment related to the provision of medical services or fraud; or

(f) Failure on the part of a physician to maintain an active, unrestricted license to practice medicine, an active, unrestricted Drug Enforcement Administration (DEA) registration, or an active, unrestricted Alabama Controlled Substances Certificate.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 16, 2020.

540-X-26-.10 Reporting Requirement

(1) Any physician engaging in Collaborative Drug Therapy Management shall be subject to disciplinary action by the Board of Medical Examiners if he or she violates the terms of this Chapter or the terms of the Agreement. Any licensing board with jurisdiction over any of the signatories to an Agreement shall report to the other appropriate board(s) any conduct which it believes to be in violation of any such Agreement.

(2) A physician in a Collaborative Drug Therapy Management Agreement which is voluntarily terminated by any party is responsible for notifying the Board of
Medical Examiners of the date on which the Agreement terminates within ten (10) days of termination. Notification to the Board of Medical Examiners by the Board of Pharmacy that a pharmacist has voluntarily terminated a collaborative practice Agreement will meet the notification requirement and will result in termination of the physician's approval to practice under the Agreement.

**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: September 16, 2020.

540-X-26-.11 **Renewal**

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

2. Each collaborating physician 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 shall be two hundred dollars ($200).

**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: September 16, 2020.