APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 680

Department or Agency: Alabama State Board of Pharmacy

Rule No.: 680-X-2-.44

Rule Title: Collaborative Practice

Intended Action: Amend

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

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule?	NA
Are all facets of the rule-making 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.

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: Anne Marie Nolen

Anne Nolen

Date: Thursday, July 18, 2024

REC'D & FILED
JUL 18, 2024
LEGISLATIVE SVC AGENCY

APA-2

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Pharmacy

RULE NO. & TITLE: 680-X-2-.44 Collaborative Practice

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:
This amendment seeks to clarify the appropriate physician to pharmacist ratios when collaborating for testing or screening for and treatment of acute, uncomplicated illness or injury.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:
The public hearing will be during the Board business meeting 9/18/24 at 9:00am CDT. Comments may be presented whether attending in-person or virtually. Comments may also be submitted beforehand via email to anolen@albop.com

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Wednesday, September 18, 2024

CONTACT PERSON AT AGENCY:
Anne Marie Nolen
anolen@albop.com

Anne Marie Nolen
Anne Nolen

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

680-X-2-.44 Collaborative Practice.

(1) **Definitions:** 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 Code of Ala. 1975, §34-24-53.

(c) "Board of Pharmacy" means the State Board of Pharmacy established pursuant to Code of Ala. 1975, §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 Collaborating Physician and the Collaborating Pharmacist 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 so that medications are taken correctly; monitor, modify, and discontinue drug therapy as directed by the physician; provide education on managing medication side effects; communicate with third party payors and insurers regarding prior authorization for prescription medications; and any other activity or service specified io a protocol approved by both the Board of Medical Examiners and the Board of Pharmacy, or otherwise authorized by this Rule.

(e) "Collaborating Pharmacist" means a pharmacist who is licensed to practice pharmacy in Alabama, who is a party to a Collaborative Drug Therapy Management Agreement, and who has a direct pharmacist-patient relationship with the patient served by the Agreement.

(f) "Collaborating Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice medicine in Alabama who is a party to a Collaborative Drug Therapy Management Agreement, who has a direct physician-patient relationship, or otherwise authorized by this Rule, with the patient served by the Agreement, and who has prepared the patient-specific, drug or drug class-specific, disease-specific, and condition-specific plan of care based on a physical examination of the patient where required under this Rule.

(g) "Covering Pharmacist" means a pharmacist licensed to practice pharmacy in Alabama who agrees in writing to be readily available to fulfill the duties of a Collaborating Pharmacist pursuant to a Collaborative Drug Therapy Management Agreement during the absence of the Collaborating Pharmacist. The Covering Pharmacist shall be an employee of

the same pharmacy practice as the Collaborating Pharmacist, demonstrate the ability to provide the services listed in the Agreement, and abide by the rules and regulations of the Board of Medical Examiners and Board of Pharmacy.
(h) "Covering Physician" means a doctor of medicine or a doctor of osteopathy licensed to practice medicine in Alabama who agrees in writing to be readily available to fulfill the duties of a Collaborating Physician pursuant to a Collaborative Drug Therapy Management Agreement during the absence of the Collaborating Physician. The covering physician shall be either a member of the same medical practice, practice group, or multidisciplinary medical team, or of the same or similar practice specialty as the Collaborating Physician and shall abide by the rules and regulations adopted by the Board of Medical Examiners and Board of Pharmacy.
(i) "Formulary" means a list of legend drugs or drug classes that may be utilized under a Collaborative Drug Therapy Management Agreement.
(j) "Joint Committee" means the Joint Committee on Pharmacy Collaborative Practice established for the purpose of enabling a mechanism for the exchange of information between the Board of Medical Examiners and the Board of Pharmacy on matters related to physician-pharmacist collaboration.
(k) "Licensed Healthcare Facility" means a hospital, as defined in Code of Ala. 1975, §22-21-20(1), licensed by the Alabama Department of Public Health, or a Federally Qualified Health Center, as defined by ALA. ADMIN. CODE r. 560-X-48-.01(1).
(l) "Patient Care Services" means services rendered by Collaborating Physicians and Collaborating Pharmacists for the benefit of the patient and which must be within the professional training and experience of the Collaborating Physician and Collaborating Pharmacist and be covered by the Collaborative Drug Therapy Management Agreement.
(m) "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 a Collaborating Pharmacist and signed by the parties to the Collaborative Drug Therapy Management Agreement.
(n) "Quality Assurance" means documented evaluation by the Collaborating Physician of the parties' adherence to the Agreement and patient outcomes against defined quality outcome measures, using a selected, meaningful sample of patient records, which will identify outcomes 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.

(o) "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, experience, and the Board of Medical Examiners' laws, rules, policies and procedures, and that of the collaborating pharmacist and his or her practice in compliance with his or her pharmacy education, training, experience, and the Board of Pharmacy's laws, rules, policies, and procedures.

(p) "Unrestricted" for the purpose of this Rule, means an active pharmacy permit, pharmacy Drug Enforcement Administration (DEA) registration, pharmacist license, medical license, and Alabama Controlled Substances Certificate that is not revoked, suspended, or on probation at the time of application 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.

(q) "Acute, uncomplicated illness or injury" means a recent or new short-term problem with low risk of morbidity for which treatment is considered and full recovery without functional impairment is expected. For the purposes of this section, an acute, uncomplicated illness or injury includes:

1. Influenza
2. Streptococcus
3. Any other condition as recommended by the Joint Committee

Under this definition, a pharmacist may use any tests which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or the federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

(2) **Collaborative Drug Therapy Management Agreement Required.**

(a) Physicians and pharmacists may only engage in Collaborative Drug Therapy Management when:

1. 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

2. 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 Collaborating Pharmacist.

(b) The patient's consent to treatment under a Collaborative Drug Therapy Management Agreement shall be made part of the patient record.

(c) The written attestation shall include the names of the Collaborating Pharmacist, Collaborating Physician, and any Covering Physician or Covering Pharmacist, if applicable, participating in the Agreement, the date of the Agreement, and a description of the scope of the services covered by the Agreement.

(d) The written attestation shall include a formulary and a list of services authorized by the Agreement.

(e) 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.

(f) 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.

(3) **Eligibility Requirements**

(a) No physician or pharmacist may engage in a Collaborative Drug Therapy Management Agreement unless each Collaborating Physician and Collaborating Pharmacist who is a party to the Agreement holds an active, unrestricted license in Alabama.

(b) 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, is not employed by a pharmacy with an unrestricted permit (where applicable), and does not comply with each term and requirement of the Board of Pharmacy's rule(s) regarding Collaborative Drug Therapy Management.

(c) No pharmacist may enter into an Agreement with a Collaborating Physician who is not licensed by the Board of Medical Examiners, does not have an active unrestricted license, and does not comply with each term and requirement of the Board of Medical Examiners' rule(s) regarding Collaborative Drug Therapy Management.

(d) A physician or pharmacist engaged in an Agreement shall have:

1. An active unrestricted license to practice medicine or pharmacy in the State of Alabama;

2. An active unrestricted Alabama Controlled Substances Certificate issued by the Board of Medical Examiners or Board of Pharmacy;

3. As to pharmacists provide services in a facility permitted pursuant to §34-23-30 only, the pharmacy must maintain an active unrestricted pharmacy permit and DEA registration;
4. As to physicians only, shall have 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
5. Paid all collaborative practice fees due to the Board of Medical Examiners and the Board of Pharmacy.

(4) **Collaborative Drug Therapy Management Agreement: Required Terms**

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

1. 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.
2. 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 acute, uncomplicated illness or injury, 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.

3. Documentation and Communication.

(i) 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 and any physician(s) designated by the patient 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.

(ii) A pharmacist performing testing or screening for and treatment of acute, uncomplicated illness or injury conditions shall also:

(I) Provide each patient with written information to advise the patient to seek follow-up care from either a physician with whom the patient has a pre-existing relationship, or,

if no pre-existing relationship exists, to seek follow-up care from the collaborating physician. (II) Provide the patient with a consent form allowing any changes to a patient's drug therapy and/or individual patient care services as set out in the Agreement to be provided to the collaborating physician and the physician with whom the patient has a pre-existing relationship.

4. 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.

5. 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.

6. 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.

7. 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:

(i) Not less than twenty-five percent (25%) of the patients treated pursuant to the Agreement for the first two years of the Agreement;

(ii) 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

(iii) 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.

8. 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 Board Rule 680-X-2-.27.

9. 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.

(b) Agreements that include the testing or screening for and treatment of acute, uncomplicated illness or injury shall also include:

1. Patient selection criteria, which shall include the physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.

2. Treatment protocols, which shall include the physician's instructions for the treatment of acute, uncomplicated illness or injury based on the patient's age, symptoms, and test results, including negative results.

3. Any other requirements as established by the Board of Pharmacy and Board of Medical Examiners.

(5) **Limitations**

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

1. Any person or patient of a Collaborating Physician for whom such Collaborating Physician has not prepared a patient- specific, drug- or drug class-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 acute, uncomplicated illness or injury, as well as the dispensing of opioid antagonists as defined in Code of Ala. 1975, §20-2-280; or

2. The prescribing of controlled substances listed or to be listed in the schedules under federal law and in Code of Ala. 1975, §§20-2-23, 20-2-25, 20-2-27, 20-2-29, and 20-2-31 and/or Board Rule 420-7-2 and its Appendix.

(b) 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.

(c) A collaborating physician may collaborate with a maximum of three collaborating pharmacists for testing or screening for and treatment of acute, uncomplicated illness or injury.

(d) A collaborating pharmacist may collaborate with a maximum of three collaborating physicians for testing or screening for and treatment of acute, uncomplicated illness or injury.

(6) **Standards for Physicians**

(a) Physicians engaged in an Agreement shall:

1. Provide professional medical oversight and instruction to the Collaborating Pharmacist;

2. Establish and/or maintain a physician-patient relationship with each patient receiving services under the Agreement, with the exception of immunizations and opioid antagonists;
3. Be readily available to the Collaborating Pharmacist through direct telecommunication for consultation, assistance, and direction, or shall make arrangements for a substitute physician to be readily available who is pre-approved by the Board of Medical Examiners, who practices in a specialty substantially similar to that of the Collaborating Physician, and who is familiar with these rules; and
4. Collaborate with pharmacist(s) who agree to be readily available to the physician through direct telecommunication for consultation, assistance, and collaboration; and
5. Contact each patient receiving treatment by a pharmacist for an acute, uncomplicated illness or injury not later than five (5) days following the first day of treatment to discuss follow-up care or refer the patient for care from a physician with whom the patient has a pre-existing relationship.

(b) In the event the Collaborating Physician is not readily available, provisions shall be made for professional medical oversight and direction by a Covering Physician who is readily available, who is pre-approved by the Board of Medical Examiners, and who is familiar with these rules. The Collaborating Physician shall certify to the Board of Medical Examiners at least annually that any approved Covering Physician continues to agree to serve in that capacity and shall inform the Board of Medical Examiners of the termination of a Covering Physician within ten (10) days of the termination.

(c) In the event of an unanticipated, permanent absence of a Collaborating Physician, a previously approved Covering Physician may be designated as a temporary Collaborating Physician for a period of up to sixty (60) days. During the sixty (60) daytime period, a new Agreement designating a new Collaborating Physician should be submitted for approval.

(7) **Standards for Pharmacists**

(a) Pharmacists engaged in an Agreement shall:
1. Establish and maintain a pharmacist-patient relationship with each patient receiving services under the Agreement;
2. Be readily available to the Collaborating Physician through direct telecommunication for consultation, assistance, and direction; and
3. Collaborate with physician(s) who agree to be readily available to the pharmacist through direct

telecommunication for consultation, assistance, and collaboration.

(b) In the event the Collaborating Pharmacist is not readily available, provisions shall be made for a Covering Pharmacist who is readily available, who is pre-approved by the Board of Pharmacy, and who is familiar with these rules. The Collaborating Pharmacist shall certify to the Board of Pharmacy at least annually that any approved Covering Pharmacist continues to agree to serve in that capacity and shall inform the Board of Pharmacy of the termination of a Covering Pharmacist within ten (10) days of the termination.

(c) In the event of an unanticipated, permanent absence of a Collaborating Pharmacist, a Covering Pharmacist may be designated as a temporary Collaborating Pharmacist for a period of up to sixty (60) days. During the sixty (60) daytime period, a new Agreement designating a new Collaborating Pharmacist should be submitted for approval.

(d) If performing testing or screening for and treatment of acute, uncomplicated illness or injury, a pharmacist shall also:

1. Provide each patient with written information to advise the patient to seek follow-up care from either a physician with whom the patient has a pre-existing relationship, or, if no pre-existing relationship exists, to seek follow-up care from the collaborating physician.

2. Upon request of a patient, furnish patient records to a physician designated by the patient.

(8) **Approval of the Collaborative Drug Therapy Management Agreement**

(a) 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.

(b) 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.

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

(d) 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.

(e) 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.

(f) 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.

(9) **Denial of an Application for a Collaborative Drug Therapy Management Agreement**

(a) The Board of Medical Examiners or Board of Pharmacy may deny approval of any Agreement based on any of the grounds specified in this Rule.

(b) Before denying an Agreement on any of the grounds specified in this Rule, the Board of Medical Examiners and/ or Board of Pharmacy shall conduct a hearing in accordance with Chapter 6 of the Rules of the Board of Medical Examiners, or pursuant to any applicable provisions of the Alabama Pharmacy Practice Act, respectively, and the Alabama Administrative Procedure Act.

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

1. Failure of a Collaborating Physician or a Collaborating Pharmacist to submit an application or Agreement that complies with the terms and requirements of this Rule;

2. A finding by the Board of Medical Examiners or Board of Pharmacy that a Collaborating Physician or Collaborating Pharmacist has submitted or caused to be submitted false, misleading, or untruthful information in connection with an application or Agreement;

3. A finding by the Board of Medical Examiners that a Collaborating or Covering Physician has committed any of the acts or offenses constituting grounds to discipline the license to practice medicine in this state pursuant to Code of Ala. 1975, §34-24-360, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of a physician under Code of Ala. 1975, §20-2-54, or that the Collaborating or Covering Physician is unable to practice Collaborative Drug Therapy Management with reasonable skill or safety to patients;

4. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has committed any of the acts or offenses constituting grounds to discipline the license to practice pharmacy in this state pursuant to Code of Ala. 1975, §34-23-33, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of the pharmacist under Code of Ala. 1975, §20-2-54, or that the Collaborating or Covering Pharmacist is unable to practice Collaborative Drug Therapy Management with reasonable skill or safety to patients;
5. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has violated the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any rules and regulations of the Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws;
6. A finding by the Board of Medical Examiners and/or the Board of Pharmacy that a party to the Agreement is under any state or federal restriction, probation, discipline, or indictment related to the provision of medical services, the practice of medicine or pharmacy, or fraud;
7. Failure on the part of a Collaborating or Covering 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; or
8. Failure on the part of a Collaborating or Covering Pharmacist to maintain an active, unrestricted license to practice pharmacy, an active, unrestricted Alabama Controlled Substances Certificate, or (where applicable), an active, unrestricted Drug Enforcement Administration (DEA) registration issued to the pharmacy which is the location for the services to be provided pursuant to the Agreement.

(10) **Grounds for Modification, Restriction, or Termination of a Collaborative Drug Therapy Management Agreement**

(a) The Board of Medical Examiners and/or Board of Pharmacy on its own motion may investigate any evidence which appears to show that its respective licensee is or may be guilty of a violation of any of the acts, offenses, or conditions set out in this Rule. A violation of this Rule is grounds for disciplinary action and sanctions against a Collaborating Physician, Collaborating Pharmacist, Covering Physician, Covering Pharmacist, or pharmacy permit, and shall be

prosecuted against and in the name of the Collaborating Physician, Collaborating Pharmacist, Covering Physician, or Covering Pharmacist participating in the alleged violation.
(b) A violation of this Rule may be sanctioned by termination, modification, or restriction of the Agreement, disciplinary action against the license of the Collaborating Physician, Collaborating Pharmacist, Covering Physician, or Covering Pharmacist, or pharmacy permit, the assessment of a fine, or any combination thereof.
(c) Before modifying, restricting, or terminating an Agreement, disciplining a license or permit, or assessing a fine, the Board of Medical Examiners and/or Board of Pharmacy shall conduct a hearing in accordance with Chapter 6 of the rules of the Board of Medical Examiners, or pursuant to any applicable provisions of the Alabama Pharmacy Practice Act, respectively, and the Alabama Administrative Procedure Act.
(d) Pursuant to the requirements of Code of Ala. 1975, §41-22-19{d), the Board of Medical Examiners or the Board of Pharmacy may order the emergency suspension of the Agreement for any of the reasons stated in this Chapter/Rule if the Board of Medical Examiners and/or Board of Pharmacy finds that danger to the public health, safety, or welfare necessitates the emergency suspension of the Agreement.
(e) An order of emergency suspension of the Agreement shall become effective immediately, unless otherwise stated in the order. Simultaneously with the issuance of an order of emergency suspension, there shall be service of a statement of charges and notice of hearing. The suspension shall be effective for a period of not longer than one hundred and twenty (120) days.
(f) The following acts shall constitute violations of this Rule:

1. Failure of a Collaborating or Covering Physician to comply with any term or requirement of this Rule or the terms of the Agreement;
2. A finding by the Board of Medical Examiners that an Agreement contains false, misleading, or untruthful information, or that a Collaborating or Covering Physician has submitted or caused to be submitted false, misleading, or untruthful information to the Board of Medical Examiners in connection with an Agreement;
3. A finding by the Board of Medical Examiners that a Collaborating or Covering Physician has committed any of the acts or offenses constituting grounds to discipline the license to practice medicine in this state pursuant to Code of Ala. 1975, §34-24-360, or any of the acts or offenses constituting grounds to discipline the

controlled substances registration of the physician under Code of Ala. 1975, §20-2-54;
4. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has committed any of the acts or offenses constituting grounds to discipline the license to practice pharmacy in this state pursuant to Code of Ala. 1975, §34-23-33, or any of the acts or offenses constituting grounds to discipline the controlled substances registration of the pharmacist under Code of Ala. 1975, §20-2-54;
5. A finding by the Board of Pharmacy that a Collaborating or Covering Pharmacist has violated the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any rules and regulations of the Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws;
6. A finding by the Board of Medical Examiners and/or the Board of Pharmacy that a party to the Agreement is under any state or federal restriction, probation, discipline, or indictment related to the provision of medical services or fraud;
7. Failure on the part of a Collaborating or Covering 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; or
8. Failure on the part of a Collaborating or Covering Pharmacist to maintain an active, unrestricted license to practice pharmacy, an active, unrestricted Alabama Controlled Substances Certificate, or, where applicable, an active, unrestricted Drug Enforcement Administration (DEA) registration issued to the pharmacy which is the location for the services to be provided pursuant to the Agreement.

(11) **Reporting Requirement**

(a) Any physician engaging in a Collaborative Drug Therapy Management Agreement shall be subject to disciplinary action by the Board of Medical Examiners if he or she violates the terms of this Rule or the terms of the Agreement. The Board of Medical Examiners shall report to the Board of Pharmacy the initiation of any proceeding against the physician or any conduct which it believes to be in violation of any such Agreement.

(b) Any pharmacist engaging in a Collaborative Drug Therapy Management Agreement shall be subject to disciplinary action by the Board of Pharmacy if he or she violates the terms of

this Rule or the terms of the Agreement. The Board of Pharmacy shall report to the Board of Medical Examiners the initiation of any proceeding against the pharmacist or any conduct which it believes to be in violation of any such Agreement.

(c) Any party to an Agreement which is voluntarily terminated shall, within ten (10) days of the termination, notify their respective board.

(d) 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. The Board of Medical Examiners shall notify the Board of Pharmacy whenever disciplinary action is taken against a Collaborating Physician's license or when a Collaborating Physician's participation in an Agreement is terminated by operation of law.

(e) If the Alabama pharmacy license of a Collaborating Pharmacist becomes inactive, revoked, suspended, restricted, or placed on probation, then that pharmacist's participation in any and all Agreements shall be administratively terminated by operation of law. The Board of Pharmacy shall notify the Board of Medical Examiners whenever disciplinary action is taken against a Collaborating Pharmacist's license or when a Collaborating Pharmacist's participation in an Agreement is terminated by operation of law.

(f) A Collaborating Physician whose Alabama medical license becomes inactive, revoked, suspended, restricted, or placed on probation, or who is administratively terminated from an Agreement shall be required to notify each party to the Agreement of said action. The Collaborating Physician shall additionally be responsible for notifying each patient served by the Agreement and shall bear the costs of such notice.

(12) **Renewal**

(a) Agreements sha11 be renewed by December 31 every two (2) years.

(b) 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 Rule.

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

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

(13) **Joint Committee**

(a) There shall be established a Joint Committee on Pharmacy Collaborative Practice for the purpose of enabling a mechanism for the exchange of information between the Board of Medical Examiners and the Board of Pharmacy on matters related to physician-pharmacist collaboration.

(b) The Joint Committee shall be composed of the following:

1. Two (2) voting members of the Board of Medical Examiners appointed by the Chairman of the Board of Medical Examiners. For the initial term, one member shall be appointed to a term concluding on December 31, 2022, and one member shall be appointed to a term concluding on December 31, 2023. Thereafter, each appointee shall serve a term of two (2) years.

2. The President and Vice-President of the Board of Pharmacy, or his or her appointee, the terms of which shall coincide with their term as President or Vice-President of the Board of Pharmacy.

(c) Members of the Joint Committee shall be eligible for reappointment. Should a vacancy occur on the Joint Committee, a successor shall be appointed by the original appointing authority to serve the unexpired term. The committee shall select one of its members to serve as chairperson for a one-year term. The chairperson shall alternate between a physician member of the committee and a pharmacist member of the committee.

(d) The Joint Committee shall not meet without the consent of both the Board of Medical Examiners and Board of Pharmacy unless all four (4) Joint Committee Members are present. The Chairman of the Board of Medical Examiners and the President of the Board of Pharmacy may appoint a proxy when necessary to ensure that each board is represented by two (2) Joint Committee members.

(e) The Joint Committee ·shall meet at least on a quarterly basis, or more or less frequently pursuant to a joint resolution by the Board of Medical Examiners and Board of Pharmacy.

(f) A member's participation in a Joint Committee meeting shall constitute official functions of and the performance of the duties of the boards and shall be eligible for the compensation, per diem, and travel allowance allowed to members of the Board of Medical Examiners under Code of Ala. 1975, §34-24-54, and members of the Board of Pharmacy under Code of Ala. 1975, §34-23-91. The Board of Medical Examiners and Board of Pharmacy shall pay compensation, per diem, and travel allowance of their respective members and shall furnish necessary clerical, legal, and administrative support for operation of the committee.

(g) The Joint Committee may exercise the following functions and responsibilities:

1. Review and/or recommend changes to the current rules and regulations for physician-pharmacist collaboration.
2. Discuss and/or make recommendations regarding changes to the standard protocol(s) adopted pursuant to Rule 680-X-2-.44(14)(a)
3. Discuss and/or make recommendations regarding changes to the standard formulary(ies) adopted pursuant to Board Rule 680-X-2-.44(15)(a).
4. Review and/or make recommendations regarding any expanded protocol requests made pursuant to Board Rule 680-X-2-.44(14)(b).
5. Review and/or make recommendations regarding any expanded formulary requests made pursuant to Board Rule 680-X-2-.44(15)(b).
6. Serve in an advisory role regarding issues related to applications for Collaborative Drug Therapy Management Agreements, required education, renewal, and other matters concerning the implementation of physician-pharmacist collaborative practice.

(h) Notwithstanding any other provision of this Rule, the Joint Committee shall serve in an advisory capacity only and any recommendation made by the Committee shall be subject to approval by both the Board of Medical Examiners and the Board of Pharmacy.

(14) **Protocols**

(a) The Board of Medical Examiners and the Board of Pharmacy shall promulgate standard protocols consistent with the recommendation of the Joint Committee establishing the patient care services that may be rendered under an Agreement.

(b) Protocols deviating from the standard protocols shall be submitted to the Joint Committee for recommendation for approval. When evaluating whether to recommend the approval or denial of a non-standard Protocol, the Joint Committee shall consider certain factors, including, but not limited to:

1. The Collaborating Physician's and Collaborating Pharmacist's education, training, experience, and specialty;
2. The Collaborating Physician's and Collaborating Pharmacist's disciplinary history and any licensure restrictions;
3. FDA approved usages and recommendations;
4. Whether a proposed Protocol is within the current standard of care for treatment of the disease or condition specified in the Protocol, including usages known as "off- label," and whether the use is supported by evidence-based research;

5. Whether the proposed Protocol creates an undue risk of harm to patients; and
6. The routine scope of practice and services provided by the Collaborating Physician and Collaborating Pharmacist.

(c) After consideration of the factors listed herein, the Joint Committee may recommend approval or denial of a non-standard Protocol in whole or in part.

(15) **Formulary**

(a) The Board of Medical Examiners and the Board of Pharmacy shall promulgate a standard formulary of legend drugs and/or drug classes consistent with the recommendations of the Joint Committee that may be utilized under an Agreement.

(b) Any Formulary that includes prescription drugs and/or drug classes additional to the standard Formulary shall be submitted to the Joint Committee for recommendation for approval. When evaluating whether to recommend the approval or denial of the addition of a drug or drug class to a Formulary, the Joint Committee shall consider certain factors, including, but not limited to:

1. The Collaborating Physician's and Collaborating Pharmacist's education, training, experience, and specialty;
2. The Collaborating Physician's and Collaborating Pharmacist's disciplinary history and any licensure restrictions;
3. FDA approved usages and recommendations;
4. Whether the usage of the proposed drug(s) or drug class(es) is within the current standard of care for treatment of the disease or condition specified in the Protocol, including usages known as "off-1abel, and whether the use is supported by evidence-based research;
5. Whether the use of the proposed drug(s) or drug class(es) creates an undue risk of harm to patients; and
6. The routine scope of practice and services provided by the Collaborating Physician and Collaborating Pharmacist.

(c) After consideration of the factors listed herein, the Joint Committee may recommend approval or denial of the addition of a drug or drug class to a Formulary.

(16) **Exclusion**

(a) The foregoing provisions of this Rule shall not apply to a pharmacist licensed by the Alabama State Board of Pharmacy who is employed by a Licensed Healthcare Facility.

(b) The Board of Medical Examiners and/or the Board of Pharmacy shall each have the authority to identify those licensees who are exempt under this Rule.

(c) The Board of Medical Examiners or the Board of Pharmacy may investigate or request additional documentation or

information from their respective licensee(s) to determine those who qualify for the exemption under this Rule.

(17) **Implementation**

(a) Any physician and/or pharmacist currently participating in any activities described by this Rule must be in full compliance with these rules no later than April 30, 2022. The provisions of this Rule shall become enforceable by the Board of Medical Examiners and Board of Pharmacy on May 1, 2022.

Author: Alabama Board of Pharmacy

Statutory Authority: Code of Ala. 1975, §34-23-77.

History: **New Rule:** Published December 31, 2019; effective February 14, 2020. **Repealed and New Rule:** Published August 31, 2021; effective October 15, 2021. **Amended:** Published February 28, 2022; effective April 14, 2022. **Amended:** Published April 28, 2023; effective June 12, 2023. **Amended:** Published November 30, 2023; effective January 14, 2024. **Amended:** Published _____; effective _____.