

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
 New Amendment Repeal Adopt by Reference

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 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: Donna Grayman
Date: 9/18/19

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(STAMP)
ALABAMA STATE BOARD OF PHARMACY

Alabama State Board of Pharmacy

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Pharmacy

RULE NO. & TITLE:

680-X-2-.44 Collaborative Practice

INTENDED ACTION:

New Rule

SUBSTANCE OF PROPOSED ACTION:

To allow a cooperative working arrangement between a physician and a pharmacist for better patient medication management.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

Oppositions can be submitted to the Alabama State Board of Pharmacy, 111 Village Street, Birmingham Alabama 35242. Office business hours are 8:00am - 4:00pm Monday through Friday. Please present your views in writing, fax or email. Public hearing will be held November 20, 2019 at 9:00am

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Comments concerning this change must be received by the Alabama State Board of Pharmacy no later than November 13, 2019

CONTACT PERSON AT AGENCY:

Wendy Passmore
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Donna C. Yeatman, R.Ph. Executive Secretary

- (1) **APPLICABILITY:** When physicians and pharmacists decide to work together in a Collaborative Practice Agreement (CPA), they do so in order to complement each other's unique roles and to make the most of their respective education and training for the patients' best interests.

Pharmacists' pharmacotherapy and patient care training combined with extensive diagnostic and patient management training of physicians can lead to effective collaborative pharmacotherapy decision making that improves patients' medication related outcomes.

Nothing in this section shall preclude a pharmacist licensed by the Board of Pharmacy employed by a licensed health care facility from executing approved medical protocols within the facility.

- (2) **DEFINITIONS.**

- (a) "Collaborative Drug Therapy Management" or "CDTM" means the initiating, monitoring, modifying, and discontinuing of a patient's drug therapy by an authorized pharmacist in accordance with a collaborative practice agreement with a physician.

CDTM may include but is not limited to obtaining a physical assessment and, in consultation with a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component.

- (b) "Collaborative Practice Agreement" or "CPA" means a written and signed agreement between a pharmacist with training and experience relevant to the scope of collaborative practice and a collaborating physician that defines the collaborative practice in which the pharmacist and physician propose to practice. The collaborative practice must be within the scope of the physician's practice. The patient shall consent to the CPA

- (c) "Initiating, monitoring, modifying, and discontinuing" means that a pharmacist may perform specific acts as authorized by the collaborating physician pursuant to the CPA. This does not include the selection of drug products not prescribed by the collaborating physician unless selection of a drug product is authorized by the written guidelines and protocols. Nothing in this definition precludes a pharmacist from substitution of

drugs or brands of drugs in compliance with Code of Alabama 1975, §34-23-8.

- (d) "Patient" means a person subject to the CPA. The collaborating physician shall assess the patient and include a diagnosis when referring the patient to the collaborating pharmacist. The patient shall be notified of, and shall consent to, the CPA services.
- (e) "Protocol" means a collaborating physician's written order, written standing medical order, or other written order of protocol. Protocol must be physician and pharmacist specific for prescriptions or orders given by the physician authorizing the written protocol. Protocol must be specific to a disease state or patient.
- (f) "Collaborating Physician" means a physician who holds an active license to practice in the State of Alabama. A collaborating physician in a CPA may only delegate to a collaborating pharmacist (or a licensed pharmacist substituting for the collaborating pharmacist if unavailable) pursuant to the written agreement and protocols with the pharmacist.
- (g) "Collaborating Pharmacist" means a pharmacist who holds a license to practice in the State of Alabama. A collaborating pharmacist in a CPA may perform CDTM with a collaborating physician (or a licensed physician substituting for the collaborating physician if unavailable) pursuant to the written agreement and protocols with the physician.

(3) **QUALIFICATIONS OF THE COLLABORATING PHARMACIST**

The collaborating pharmacist shall have:

1. A current, unrestricted license to practice pharmacy in the state of Alabama;
2. Paid all collaborative practice fees due to the Alabama Board of Pharmacy;
3. Adequate training and/or experience for the execution of the CPA as determined by the Board.

(4) **REQUIREMENTS**

- (a) A qualifying pharmacist may implement, monitor and modify drug therapy and use only under the following circumstances:

1. The patient's drug therapy and use are pursuant to a CPA with a collaborating physician.
2. The pharmacist follows the written CPA protocols prescribed by the collaborating physician who made the diagnosis and implements, monitors or modifies a patient's drug therapy and use only pursuant to those protocols.
3. Compliance with any other requirement deemed necessary by the Board

(b) A CPA must include:

1. Health, wellness, preventative and disease state(s) being managed, with each disease state identified as either primary or co-morbid;
2. Specific pharmacist prescribing authority pursuant to the agreement;
3. Detailed practice protocols;
4. Description of risk management activities;
5. Documentation of any initiation, modification, or discontinuation of a patient's medication in the patient's medical record in the custody of the collaborating physician;
6. Description of outcome measurements;
7. Protocol to dictate the method, manner and time for communication of the needs of patients;
8. Detailed process for continuation of the patient's drug therapy should the CPA be terminated or not renewed.

(c) A collaborative practice agreement must be submitted to the Alabama Board of Pharmacy and the Alabama Board of Medical Examiners within 10 days after the agreement is signed by both parties. The Alabama Board of Pharmacy and the Alabama Board of Medical Examiners must approve the CPA prior to the initiation of the agreement.

1. The initial application for approval by a collaborating pharmacist for a CPA will be submitted to the Alabama Board of Pharmacy with a fee of \$100.

2. Renewal applications by a collaborating pharmacist for a CPA will be submitted to the Alabama Board of Pharmacy with a fee of \$50.

- (d) Any changes or adjustments to a currently approved CPA must be provided to the Alabama Board of Pharmacy and the Alabama Board of Medical Examiners for approval prior to initiation of the changes to the agreement.
- (e) A collaborative practice agreement must be reviewed and renewed by the collaborating pharmacist and collaborating physician every 2 years.
- (f) A copy of the collaborative practice agreement with any supporting documentation and/or patient information must be kept in a readily retrievable form at the pharmacy for a minimum of 2 years.
- (g) A physician that enters into a CPA must have an ongoing legitimate physician-patient relationship with the patient. For purposes of this subsection, a "physician-patient" relationship based on:
 - 1. The patient making a medical complaint,
 - 2. The patient providing a medical history,
 - 3. The patient receiving a physical examination, and
 - 4. A logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient.
- (h) A pharmacist is responsible for the pharmacist's negligent acts that are the result of the pharmacist's change of medication or that relate to patient drug usage pursuant to drug therapy management protocols. This subsection does not limit the physician's liability for negligent acts that are not related to a pharmacist's change of medication pursuant to the protocols.
- (i) Nothing in this section may be interpreted to permit an alteration of a physician's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, and/or the practice of medicine, unless otherwise permitted by the CPA.
- (j) A licensee who violates this rule commits an act of unprofessional conduct.
A physician or physician group may hire pharmacists for the purpose of practicing CDTM under a CPA, as defined in subsection 3, for the benefit of a patient of that physician or physician group. A retail pharmacy may

employ a physician except for the purpose of maintaining, establishing, or entering a CPA.

- (k) In the event the collaborating pharmacist is not readily available, provisions shall be made by the pharmacist for coverage by a pharmacist who is pre-approved by the Board of Pharmacy and familiar with these rules.
- (l) In the event of an unanticipated, permanent absence of the collaborating pharmacist, a previously approved covering pharmacist may be designated as a temporary collaborating pharmacist for a period of up to sixty (60) days. During the sixty (60) day time period, a new CPA designating a new collaborating pharmacist should be submitted for approval.

(5) **TERMINATION OF A COLLABORATIVE PRACTICE AGREEMENT**

- (a) Prior to termination or non-renewal of a CPA, the collaborating physician and the collaborating pharmacist shall arrange for uninterrupted continuation of the patient's drug therapy, in accordance with the terms of the CPA.
- (b) When a CPA is not renewed or the CPA is otherwise terminated, the collaborating pharmacist and collaborating physician shall inform all active patients in writing of the termination and of the procedures in place for continuation of the patient's drug therapy, in accordance with the terms of the CPA.
- (c) The collaborating pharmacist and collaborating physician shall each inform their respective board in writing of the effective date of the termination of the CPA and the reasons for such termination. Failure to notify the respective board of termination may be considered a violation of these rules and regulations.
- (d) The collaborating physician has an ongoing responsibility for patient care unless or until the physician patient relationship is terminated.

(6) **GROUND FOR DENIAL OF A PERMIT OF APPROVAL OF THE COLLABORATIVE PRACTICE AGREEMENT**

- (a) Any prior discipline imposed on the collaborating pharmacist by the Alabama Board of Pharmacy or by any other board of pharmacy, shall be grounds, within the discretion of the board, to deny an application of the pharmacist.

(b) A violation of 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 Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws, and/or the commission by the collaborating physician of any act, offense or condition set forth in Code of Alabama 1975, §34-24-57 and §34-24-360, shall be grounds, within the discretion of the respective board, to deny an application of the pharmacist or physician.

(c) If upon examination of the application for approval and after consideration of any information acquired by the Board of Pharmacy and/or the Board of Medical Examiners pursuant to an investigation into the qualifications of the pharmacist or physician, either board determines there is probable cause to believe there exists one or more grounds upon which the application may be denied, then the respective board shall:

1. Notify the pharmacist and/or physician of the grounds for possible denial of approval and the procedure for obtaining a hearing before the respective board. The failure to request a hearing within the time specified in the notice shall be deemed a waiver of such hearing.
2. All hearings under this rule shall be conducted pursuant to the Alabama Pharmacy Practice Act and Alabama Administrative Practice Act.

(7) GROUNDS FOR SANCTION

(a) The Board of Pharmacy may deny, suspend, or revoke the license of a pharmacist and/or impose a fine (not to exceed \$1000 per violation) for cause set forth in 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 Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any applicable laws.

(b) The Board of Medical Examiners may seek the denial, suspension, or revocation of a license of a physician for any cause set forth in Code of Alabama 1975, as amended, §34-24-57 and §34-24-360 and any rules promulgated pursuant to law.

(8) **GROUNDS FOR TERMINATION / TERMINATION OF APPROVAL OF A
COLLABORATIVE PRACTICE AGREEMENT**

- (a) A violation of 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 Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any applicable laws, including , but limited to this rule.

- (b) Before terminating the permit of approval by the State Board of Pharmacy of a CPA on any of the grounds specified in this section, the State Board of Pharmacy shall conduct a hearing under the provisions of the Alabama Pharmacy Practice Act and the Alabama Administrative Procedures Act.

- (c) Pursuant to the requirements of §41-22-19(d) of the Code of Alabama, 1975, the State Board of Pharmacy may issue an emergency suspension of the permit of approval for a collaborating practice agreement without a hearing if the Board finds that continued operation or activities set out in the CPA by the pharmacist is a danger to the public health, safety or welfare.

- (d) An order of emergency suspension of a CPA shall become effective immediately, unless otherwise stated in the order. The suspension may be effective for a period of not to exceed one hundred twenty (120) days or until a final order is issued by the Board of Pharmacy after notice and hearing pursuant to Alabama Pharmacy Practice Act and Alabama Administrative Practice Act.

Author: Donna C. Yeatman R.Ph. Executive Secretary

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed