ALABAMA BOARD OF MEDICAL EXAMINERS
ADMINISTRATIVE CODE

CHAPTER 540-X-26
COLLABORATIVE PHARMACY PRACTICE

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

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

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

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

(c) Documentation and Communication.

1. 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.

2. 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.

(d) Override Clause. A provision must be included in the Agreement providing for the Collaborating Physician to override the actions taken by the Collaborating Pharmacist specific to services provided under the Agreement. This provision must state how such overrides shall be documented

and communicated to the Collaborating Pharmacist and the patient in a timely manner, as defined in the Agreement.

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

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

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

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

2. Not less than ten percent (10%) of the patients treated pursuant to the Agreement after the Agreement has been in effect for two years; and

3. All adverse outcomes of the patients treated pursuant to the Agreement.

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

(h) All Agreements shall require the Collaborating Pharmacist to use an area for in-person or other approved consultations with patients that ensures the confidentiality of the communication and complies with the requirements and standards set forth by the Board of Pharmacy in Ala. Admin. Code r. 680-X-2-.27.

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

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

(a) 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.

(b) 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.

(c) Any other requirements as established by the Board of Pharmacy and Board of Medical Examiners.

Author: Alabama Board of Medical Examiners
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