Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.29 Drug Therapy Management

Authority: Health Occupations Article, §§12-6A-01 – 12-6A-10, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Amendment” means a change to:

(a) A protocol or prescriber-pharmacist agreement; or

(b) The parties to the prescriber-pharmacist agreement.

(2) “Applicants” means physicians, pharmacists, podiatrists, or certified advanced practice nurses with prescriptive authority submitting a prescriber-pharmacist agreement and protocol to their respective Boards.

(2-1) “Authorized prescriber” means a licensed physician, licensed podiatrist, or certified advanced practice nurse with prescriptive authority under Health Occupations Article, §8-508, Annotated Code of Maryland.

(3) “Boards” means the Board of Physicians, the Board of Pharmacy, the Board of Podiatric Medical Examiners, and the Board of Nursing.

(4) "Condition" means a disease-state or health circumstance necessitating monitoring or intervention.

(5) "Emergency first care" means triage of emergent conditions or treatment of the condition in those cases in which a protocol specifies treatment for the emergent condition.

.02 Content of Protocol.

A. A protocol shall:

(1) Be:

(a) Written; and

(b) Condition or disease-state specific; and

(2) Contain the following:

(a) The condition that the protocol is designed to manage;

(b) A list of medications that may be used under the auspices of the protocol;

(c) Monitoring parameters including laboratory tests for the:

(i) Condition; and

(ii) Medication employed;

(d) A list of circumstances requiring contact with the authorized prescriber or authorized prescribers who are a party to the prescriber-pharmacist agreement;

(e) A statement prohibiting substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the authorized prescriber unless permitted in the therapy management contract;

(f) A list of circumstances under which the pharmacist may alter doses, modify the treatment regimen, or switch the agent under the terms of the therapy management contract;

(g) Information to be documented;

(h) A listing of provisions within the protocol that may be customized within a therapy management contract; and

(i) An action plan for situations when the pharmacist encounters a situation that is not addressed in the protocol.

B. A protocol may authorize:

(1) The modification, continuation, and discontinuation of drug therapy;

(2) The ordering of laboratory tests;

(3) Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy; and

(4) For protocols by a licensed physician and licensed pharmacist, the initiation of drug therapy under written, disease-state specific protocols.

C. A protocol may not authorize acts that exceed the scope of practice of the parties to the prescriber-pharmacist agreement.

D. Technical modifications to the protocol shall be registered with the Board of Pharmacy within 30 days of the technical modification.

.03 Content of Prescriber-Pharmacist Agreement.

A. The prescriber-pharmacist agreement shall contain the following:

(1) The names and signatures of the physicians, podiatrists, or certified advanced practice nurses with prescriptive authority and pharmacists authorized to act under a therapy management contract;

(2) The locations where the pharmacists may provide therapy management services;

(3) The titles of the protocols to which the prescriber-pharmacist agreement pertains;

(4) The methods and time frames by which documentation and routine communication will occur between the physicians, podiatrists, or certified advanced practice nurses with prescriptive authority and the pharmacists, including the time frames in which the pharmacist will fully update the patient's record in writing;

(5) The name, address, and telephone number of the party to the prescriber-pharmacist agreement who is to receive correspondence from the Boards related to the prescriber-pharmacist agreement;

(6) A statement that the physicians, podiatrists, or certified advanced practice nurses with prescriptive authority and pharmacists shall comply with all State and federal laws relating to patient confidentiality; and

(7) A list of devices available to the pharmacists performing under the prescriber-pharmacist agreement, which are relevant to the disease-states or conditions to be managed.

B. Technical modifications to the prescriber-pharmacist agreement shall be registered with the Board of Pharmacy within 30 days of the technical modification.

C. The party designated as the contact person to receive correspondence from the Boards shall ensure that the parties to the prescriber-pharmacist agreement are notified in a timely manner of the information received from the Boards.

D. If the contact information for the party to the agreement designated to receive correspondence from the Boards changes, the designee shall notify the Boards of the change within 30 days of the change.

.04 Requirements for Participation in Drug Therapy Management.

A. In order to enter into a therapy management contract, a pharmacist:

(1) Shall be licensed by and in good standing with the Board of Pharmacy;

(2) Shall possess a Doctor of Pharmacy degree or equivalent training as established in §B of this regulation;

(3) May not have:

(a) A public final order by the Board of Pharmacy disciplining the pharmacist's license within the 5 years immediately before the application is submitted; or

(b) Limitations placed on the pharmacist's license by the Board of Pharmacy in a public order;

(4) Shall possess relevant advanced training as indicated by one of the following:

(a) Certification as a specialist related to the disease state specified by the protocol by:

(i) The Board of Pharmacy Specialties;

(ii) The American Society of Consultant Pharmacist's Certified Geriatric Practitioner certification program; or

(iii) Another credentialing body approved by the Board of Pharmacy; or

(b) Successful completion of:

(i) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council for Pharmacy Education;

(ii) A certificate program approved by the Board of Pharmacy;

(iii) A National Association of Boards of Pharmacy credentialing examination; or

(iv) An examination approved by the Board of Pharmacy;

(5) Shall have successfully completed:

(a) 1,000 hours of relevant clinical experience; or

(b) 320 hours in a structured experience program approved by the Board of Pharmacy; and

(6) Shall document training related to the disease state specified in the protocol.

B. A pharmacist who does not possess a Doctor of Pharmacy degree shall document that the pharmacist's training has included the following components:

(1) Designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care;

(2) Identifying, assessing, and solving medication-related problems, and providing clinical judgments as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;

(3) Conducting appropriate physical assessments, evaluating patient problems, and ordering and monitoring medications and laboratory tests in accordance with established standards of practice;

(4) Monitoring patients and patient populations regarding the purposes, uses, effects, and pharmacoeconomics of their medications and related therapy;

(5) Providing emergency first care, including cardiopulmonary resuscitation;

(6) Using clinical data to optimize therapeutic drug regimens; and

(7) Documenting interventions and evaluating pharmaceutical care outcomes.

C. The Board of Pharmacy shall determine whether the pharmacist meets the requirements of §§A and B of this regulation.

D. An authorized prescriber who has entered into a prescriber-pharmacist agreement shall submit to the Boards that regulate the authorized prescriber a copy of:

(1) The prescriber-pharmacist agreement;

(2) Subsequent amendments made to the:

(a) Prescriber-pharmacist agreement; or

(b) Protocols specified in the prescriber-pharmacist agreement; and

(3) Changes to participants of the:

(a) Prescriber-pharmacist agreement; or

(b) Protocols specified in the prescriber-pharmacist agreement.

E. The Boards that regulate the authorized prescriber shall notify the authorized prescriber of any additional information needed within 30 days of the receipt of the submitted information.

F. A licensed pharmacist who has entered into a prescriber-pharmacist agreement shall submit to the Board of Pharmacy a copy of:

(1) The prescriber-pharmacist agreement;

(2) Subsequent amendments made to the:

(a) Prescriber-pharmacist agreement; or

(b) Protocols specified in the prescriber-pharmacist agreement; and

(3) Changes to participants of the:

(a) Prescriber-pharmacist agreement; or

(b) Protocols specified in the prescriber-pharmacist agreement.

G. The Board of Pharmacy shall determine whether a pharmacist added under §F of this regulation meets the requirements of §§A and B of this regulation.

H. The Board of Pharmacy shall notify the pharmacist of any additional information needed within 30 days of the receipt of the submitted information.

.05 Guidelines for Use of Protocols.

A. On receipt of specific instructions from the authorized prescriber regarding a specific patient, the pharmacist may execute the authorized prescriber's specific instructions even if the instructions deviate from the protocol.

B. The protocol may not prohibit the pharmacist from providing other pharmaceutical services that are within the pharmacist's scope of practice.

C. Documentation of activities performed under a protocol or the authorized prescriber's specific instructions shall be maintained in such a manner that it is accessible to the:

(1) Authorized prescriber; and

(2) Pharmacist.

D. Documentation may be maintained in written or electronic form.

E. Oral communications between the authorized prescriber and pharmacist shall be summarized in the documentation maintained by the pharmacist and forwarded to the authorized prescriber.

F. Unless an alternative time period is stated in the prescriber-pharmacist agreement, the pharmacist shall inform the authorized prescriber within 48 hours if the pharmacist:

(1) Modifies the dose or agent under the therapy management contract;

(2) Detects an abnormal result from an assessment activity; or

(3) Initiates drug therapy under a written, disease-state specific protocol, for protocols by a licensed physician and pharmacist.

.06 Therapy Management Contracts.

A. A therapy management contract shall be signed by the:

(1) Authorized prescriber or authorized prescribers involved in the management of the patient under a prescriber-pharmacist agreement;

(2) Pharmacist or pharmacists involved in the management of the patient under a prescriber-pharmacist agreement; and

(3) Patient receiving care under the therapy management contract.

B. A therapy management contract shall contain:

(1) A list of allowable substitutions of chemically dissimilar drugs, if any;

(2) A statement that:

(a) None of the parties involved in the therapy management contract have been:

(i) Coerced into participating in the therapy management contract;

(ii) Given economic incentives, excluding normal reimbursement for services rendered; or

(iii) Involuntarily required to participate in the therapy management contract; and

(b) The pharmacist shall notify the authorized prescriber under the terms of the prescriber-pharmacist agreement if the pharmacist:

(i) Modifies the dose or agent under the therapy management contract; or

(ii) Detects an abnormal result from an assessment activity;

(3) Notice to the patient stating:

(a) That the patient may terminate the therapy management contract at any time; and

(b) The procedure by which the patient may terminate the therapy management contract;

(4) A procedure for periodic review by the authorized prescriber of the drugs modified under the prescriber-pharmacist agreement or changed with the consent of the authorized prescriber;

(5) A reference to the protocol or protocols under which the pharmacist shall act; and

(6) Exceptions or limitations to the protocol or protocols for the specific patient.

.07 Fees.

A. Scope. This regulation governs authorized prescribers and pharmacists participating in drug therapy management or amendment of authorized prescribers and pharmacists that participate in the prescriber-pharmacist agreements relating to drug therapy management.

B. Fees. The Board of Pharmacy requires a fee for the prescriber-pharmacist agreement and protocol application (which includes review of the qualifications of the pharmacist participants) of $100 per prescriber-pharmacist agreement.