

## Chapter 5. Pharmacists

### §523. Collaborative Drug Therapy Management

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

*Board*—the Louisiana Board of Pharmacy.

*Collaborative Drug Therapy Management*—that practice in which a pharmacist, to the extent authorized by a collaborative drug therapy management agreement, voluntarily agrees with a physician registered with the Louisiana State Board of Medical Examiners, to manage the disease specific drug therapy of one or more patients of such physician, within a predetermined range of medication selected by the physician and set forth in a written protocol. Drug therapy management shall be limited to:

- a. monitoring and modifying a disease specific drug therapy;
- b. collecting and reviewing patient history;
- c. obtaining and reviewing vital signs, including pulse, temperature, blood pressure, and respiration;
- d. ordering, evaluating, and applying the results of laboratory tests directly related to the disease specific drug therapy being managed under written protocol, provided such tests do not require the pharmacist to interpret such testing or formulate a diagnosis;
- e. administration of vaccines to a patient 16 years of age or older by a pharmacist authorized to administer vaccines by the board;
- f. providing up to a single seven day supply of a single drug after all refills authorized on the original prescription issued to the patient by the patient's physician have been dispensed; and
- g. providing disease or condition specific patient education and counseling.

*Collaborative Drug Therapy Management Agreement*—a written document in which a pharmacist and a physician identify the terms and conditions under which they voluntarily agree to participate in collaborative drug therapy management.

*Controlled Substance*—any substance defined, enumerated, or included in federal or state statute or regulations, or any substance which may hereafter be

designated as a controlled substance by amendment or supplementation of such statute or regulations.

*Disease Specific Drug Therapy*—a specific drug or drugs prescribed by a physician for a specific patient of such physician that is generally accepted within the standard of care for treatment of one of the following diseases or conditions:

- a. treatment and prevention of arterial and venous clot propagation and disease, i.e., anti-coagulant therapy;
- b. treatment and prevention of diabetes;
- c. adjustment of medication administered by inhalant for treatment of asthma;
- d. treatment and prevention of dyslipidemia;
- e. smoking cessation therapy;
- f. administration of disease specific vaccines to patients 16 years of age or older; and
- g. such other drugs, diseases or conditions as may be subsequently recommended by the advisory committee and approved by the board.

*Drug*—

- a. any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals;
- b. any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or other animals; or
- c. any substance other than food intended to affect the structure or any function of the body of humans or other animals.

*Drugs of Concern*—a drug that is not a controlled substance but which is nevertheless defined and identified, in accordance with the procedures established by the Louisiana Prescription Monitoring Program Act, R.S. 40:1001-1014, as a drug with the potential for abuse.

*Pharmacist*—an individual currently licensed by the board to engage in the practice of pharmacy in the state.

*Physician*—an individual lawfully entitled to engage in the practice of medicine in this state as evidenced by a current, unrestricted license duly issued by the Louisiana State Board of Medical Examiners.

*Prescribe*—a request or order transmitted in writing, orally, electronically or by other means of telecommunication for a drug that is issued in good faith, in the usual course of professional practice and for a legitimate medical purpose, by a physician for the purpose of correcting a physical, mental, or bodily ailment of his patient.

*Written Protocol*—a written set of directives or instructions containing each of the components specified elsewhere in this Section for collaborative drug therapy management of disease specific drug therapy for a specific patient. The written protocol shall be signed by the physician and represents the physician orders for the collaborative drug therapy management to be provided to the patient.

## B. Registration

### 1. Eligibility

a. No pharmacist shall engage in collaborative drug therapy management in this state until registered with the board in accordance with this Section. To be eligible for registration, a pharmacist shall, as of the date of the application:

- i. possess a current, unrestricted license to practice pharmacy issued by the board and not be the subject of a pending investigation or complaint by the board or by the pharmacy licensing authority of any other state or jurisdiction;
- ii. be actively engaged in the practice of pharmacy in this state and the provision of pharmacist care similar to the activities anticipated in the collaborative drug therapy management agreement.

b. A pharmacist shall be deemed ineligible for registration of collaborative drug therapy management who:

- i. does not possess the qualifications prescribed by §523.B.1(a);
- ii. has voluntarily surrendered or had suspended, revoked, or restricted, his controlled dangerous substances license, permit, or registration (state or federal);
- iii. has had a pharmacy license suspended, revoked, placed on probation or restricted in any manner by the board or by the pharmacy licensing authority of any other state or jurisdiction;
- iv. has had an application for pharmacist licensure rejected or denied; or
- v. has been, or is currently in the process of being denied, terminated, suspended, refused, limited, placed on probation or under other disciplinary action

with respect to participation in any private, state, or federal health insurance program.

c. The board may, in its discretion, waive the limitations referenced in Subparagraph B.1.b of this Section on a case-by-case basis.

d. The board may deny registration to an otherwise eligible pharmacist for any of the causes enumerated in R.S. 37:1241.A, or any other violation of the provisions of the Pharmacy Practice Act or the board's rules.

e. The burden of satisfying the board as to the eligibility of a pharmacist for registration to engage in collaborative drug therapy management shall be upon the pharmacist. A pharmacist shall not be deemed to possess such qualifications unless and until the pharmacist demonstrates and evidences such qualifications in the manner prescribed by and to the satisfaction of the board.

### 2. Application and Issuance

a. Application for registration to engage in collaborative drug therapy management shall be made upon forms supplied by the board. Application forms and instructions may be obtained from the board's website at [www.labp.com](http://www.labp.com) or by contacting the board's office.

b. An application for registration to engage in collaborative drug therapy management shall include:

- i. the pharmacist's full name, license number, mailing address of record, and emergency contact information;
- ii. a description of the pharmacist's professional education that qualifies him to engage in collaborative drug therapy management activities described in the agreement;
- iii. proof documented in a form satisfactory to the board that the pharmacist possesses the qualifications set forth in this Section;
- iv. a fully executed copy of a collaborative drug therapy management agreement conforming to the requirements of this Section;
- v. confirmation the pharmacist shall only engage in collaborative drug therapy management to the extent detailed in the agreement and in accordance with the rules of the board; and
- vi. such other information and documentation as the board may require to evidence qualification for registration.

c. The board may reject or refuse to consider any application for registration which is not complete

in every detail required by the board or may refuse to consider a collaborative drug therapy management agreement which fails to comply with the minimum requirements of this Section. The board may, in its discretion, require a more detailed or complete response to any request for information set forth in the application as a condition to consideration.

d. A pharmacist seeking registration to engage in collaborative drug therapy management shall be required to appear before the board or its designee if the board has questions concerning the nature or scope of the pharmacist's application, finds discrepancies in the application, or for other good cause as determined by the board.

e. When all the qualifications, requirements, and procedures of this Section are met to the satisfaction of the board, the board shall approve and register a pharmacist to engage in collaborative drug therapy management. Registration of authority to engage in collaborative drug therapy management shall not be effective until the pharmacist receives notification of approval from the board.

f. Although a pharmacist shall notify the board each time he intends to engage in collaborative drug therapy management with a physician other than the physician identified in the pharmacist's original application, registration with the board is only required once. The board shall maintain a list of pharmacists who are registered to engage in collaborative drug therapy management.

g. Each pharmacist registered to engage in collaborative drug therapy management shall be responsible for updating the board within 10 days in the event of any change in the information recorded in the original application.

### 3. Expiration of Registration; Renewal

a. A pharmacist's registration to engage in collaborative drug therapy management with a physician shall terminate and become void, null and without effect upon the earlier of:

i. death of either the pharmacist or physician;

ii. loss of license of either the pharmacist or physician;

iii. disciplinary action limiting the ability of either the pharmacist or the physician to enter into collaborative drug therapy management;

iv. notification to the board that either the pharmacist or physician has withdrawn from collaborative drug therapy management;

v. a finding by the board of any of the causes that would render a pharmacist ineligible for registration; or

vi. expiration of a pharmacist's license or registration to engage in collaborative drug therapy management for failure to timely renew such license or registration.

b. Registration of authority to engage in collaborative drug therapy management shall expire annually on the same day as a pharmacist's license unless renewed by the pharmacist by submitting an application to the board upon forms supplied by the board, together with verification of the accuracy of registration and collaborative drug therapy management agreement information on file with the board. An application for registration renewal shall be made part of and/or accompany a pharmacist's renewal application for pharmacist licensure.

c. The timely submission of an application for renewal of a registration shall operate to continue the expiring registration in effect pending renewal of registration or other final action by the board on such application for renewal.

C. Advisory Committee. The Collaborative Drug Therapy Management Advisory Committee, constituted as provided for in LAC 46:XLV.7417, shall assist the Board of Medical Examiners and the Board of Pharmacy on matters relative to collaborative drug therapy management. The President of the Board of Pharmacy shall appoint a pharmacist to serve on the committee, and said pharmacist shall serve at the pleasure of the Board of Pharmacy.

### D. Standards of Practice

1. Authority, Responsibility, and Limitations of Collaborative Drug Therapy Management

a. A pharmacist registered with the board under this Section may engage in collaborative drug therapy management with a physician:

i. to the extent authorized by a collaborative drug therapy management agreement filed with approved by the board; and

ii. in accordance with a patient specific, drug specific, disease specific written protocol, satisfying the requirements of this Section.

b. A pharmacist engaged in collaborative drug therapy management shall:

i. retain professional responsibility to his patient for the management of his drug therapy;

ii. establish and maintain a pharmacist-patient relationship with each patient subject to the collaborative drug therapy management agreement;

iii. be geographically located to be physically present to provide pharmacist care to a patient subject to collaborative drug therapy management;

iv. provide on a schedule defined in the written protocol, a periodic status report on the patient, including but not limited to, any problem, complication, or other issues relating to patient non-compliance with drug therapy management; and

v. be available through direct telecommunication for consultation, assistance, and direction.

c. A pharmacist's registration to engage in collaborative drug therapy management with a physician is personal to the pharmacist. A registered pharmacist shall not allow another pharmacist or any other individual to exercise the authority conferred by such registration. A registered pharmacist shall not engage in collaborative drug therapy management with a non-physician or with any physician who is not a party to the pharmacist's collaborative drug therapy management agreement on file with the board.

d. Collaborative drug therapy management shall only be utilized for those conditions or diseases identified in, and in the manner specified by, this Section. Additional conditions or diseases for which there are generally accepted standards of care for disease specific drug therapy may be identified by the advisory committee and approved by the board.

e. Only a pharmacist who holds the academic degree of Doctor of Pharmacy, which degree provided specific training in the area of anti-coagulant drug therapy, shall engage in collaborative drug therapy management in such particular area of practice covered by a collaborative drug therapy management agreement. The board may, in its discretion, grant an exception to this limitation on a case-by-case basis to a pharmacist who does not possess the academic degree required by this Section upon the affirmative recommendation and advice of the advisory committee that the pharmacist possesses the equivalent or other acceptable advanced training in the area of practice covered by the agreement.

f. The scope of the collaborative drug therapy management shall not include:

i. any patient of the physician for whom such physician has not prepared a patient specific, drug specific, disease specific written protocol;

ii. drug therapy management of more than one specific disease or condition. Administration of a vaccine or smoking cessation therapy is excepted from this provision;

iii. drug therapy management of any patient by more than one registered physician and one pharmacist;

iv. any patient under the age of 18 years of age. Administration of a vaccine or smoking cessation therapy is excepted from this provision.

v. pregnant or nursing mothers;

vi. initiation or discontinuance of drug therapy by a pharmacist, except as specified in the written protocol;

vii. the management of controlled substances or drugs of concern; or

viii. substitution of a drug prescribed by a physician without the explicit written consent of such physician.

## 2. Informed Consent

a. A pharmacist shall not engage in collaborative drug therapy management of a patient without the patient's written informed consent.

b. In addition to the requirements provided by law for obtaining a patient's informed consent, each patient who is subject to a collaborative drug therapy management agreement shall be:

i. informed of the collaborative nature of drug therapy management for the patient's specific medical disease or condition and provided instructions and contact information for follow-up visits with the pharmacist and physician;

ii. informed he may decline to participate in a collaborative drug therapy management practice and may withdraw at any time without terminating the physician-patient or pharmacist-patient relationship; and

iii. provided written disclosure of any contractual or financial arrangement with any other party that may impact one of the party's decision to participate in the agreement.

c. All services provided pursuant to a collaborative drug therapy management agreement shall be consistent with the agreement and shall be performed in a setting which insures patient privacy and confidentiality.

## 3. Collaborative Drug Therapy Management Agreement

a. A collaborative drug therapy management agreement shall, at a minimum, include:

i. the name, professional license number, address or addresses, telephone/cell phone number, e-mail address, and emergency contact information for the pharmacist and physician, and the date of signing and termination of the agreement;

ii. a description of the manner and circumstances under which the pharmacist and physician shall engage in collaborative drug therapy management;

iii. the condition or disease to be managed;

iv. the specific drug or drugs to be utilized for such condition or disease;

v. the drug therapy management activities, as defined in this Section, to be performed by the pharmacist as authorized by the physician;

vi. the procedure to be followed by the parties for drug therapy management and a plan of accountability defining the respective responsibilities of the pharmacist and physician;

vii. a plan for reporting and documenting drug therapy management activities in the pharmacy and medical records and schedule by which such are to take place. A pharmacist shall submit a report to the collaborating physician at least every 30 days, or more frequently if warranted by clinical conditions, regarding the status of a patient's collaborative drug therapy management, with such report made a part of the pharmacy record for such patient;

viii. a plan for record keeping, record sharing, and record storage. The agreement shall acknowledge all collaborative drug therapy management records shall be treated as and governed by the laws applicable to physician medical records;

ix. acknowledgement each patient subject to the agreement shall be notified that a collaborative drug therapy management agreement exists, describes the procedures for obtaining informed consent of such patient, and the plan to address patient needs when both the pharmacist and physician are absent from the practice setting; and

x. the procedure and schedule for reviewing and assessing the quality of care provided to each patient subject to collaborative drug therapy management under written protocol.

b. In the event the physician authorizes the pharmacist to order, evaluate, and apply the results of a laboratory test or tests directly related to disease specific drug therapy being managed under written

protocol, the agreement shall identify the specific test or tests and describe the plan for securing such testing.

c. The agreement shall affirm that:

i. collaborative drug therapy management shall be in conformity with generally accepted standards of care for treatment of a patient's specific disease or condition;

ii. all services provided pursuant to a collaborative drug therapy management shall be consistent with the agreement and performed in a setting that insures patient privacy and confidentiality; and

iii. a copy of the agreement shall be maintained on site by the respective parties.

d. The agreement may include the identity of one back-up pharmacist possessing the qualifications for collaborative drug therapy management required by this Section, who shall serve in the absence of the registered pharmacist to the agreement. The identifying information specified in this Section shall be provided for such pharmacist, along with and acknowledgement of responsibility to adhere to the same obligations and commitments imposed on the registered pharmacist to the agreement, as evidenced by a dated signature.

e. An agreement is valid for a period of time not to exceed one year. A collaborating pharmacist shall insure that a collaborative drug therapy management agreement is annually reviewed, updated as appropriate, signed by the pharmacist and physician.

f. Each registered pharmacist is responsible for updating the board within 10 days in the event any of the information required and submitted in accordance with this Section changes after the board has approved the agreement.

#### 4. Written Protocols

a. A separate protocol shall be written for each patient to be managed by collaborative drug therapy management. A copy of each written protocol shall be:

i. provided to the collaborating physician and pharmacist;

ii. made part of the patient's pharmacy record; and

iii. appended by the pharmacist to the collaborative drug therapy management agreement with the physician and maintained in a separate file at the pharmacist's practice site listed on the pharmacist's registration on file with the board.

b. A physician shall develop a patient specific written protocol for a particular patient or utilize a standard written protocol, incorporating what patient specific deviations, if any, the physician may deem necessary or appropriate for such patient. In either event, a written protocol for disease specific drug therapy shall adhere to generally accepted standards of care and shall identify, at a minimum:

i. the pharmacist, the physician, and telephone number and other contact information for each;

ii. the patient's name, address, gender, date of birth, and telephone number;

iii. the disease or condition to be managed;

iv. the disease specific drug or drugs to be utilized;

v. the type and extent of drug therapy management the physician authorizes the pharmacist to perform;

vi. the specific responsibilities of the pharmacist and physician;

vii. the procedures, criteria, or plan the pharmacist is required to follow in connection with drug therapy management;

viii. the specific laboratory test or tests, if any, directly related to drug therapy management the physician authorizes the pharmacist to order and evaluate;

ix. the reporting and documentation requirements of the pharmacist and physician respecting the patient and schedule by which such are to take place;

x. the conditions and events upon which the pharmacist and physician are required to notify one another; and

xi. procedures to accommodate immediate consultation by telephone or direct telecommunication with, between or among the pharmacist, physician, and the patient.

c. Each written protocol utilized for collaborative drug therapy management of a patient shall be reviewed annually by the collaborating pharmacist, or more frequently as such pharmacist deems necessary, to address patient needs and to insure compliance with the requirements of this Section. A collaborating pharmacist's signature and date of review shall be noted on the written protocol and maintained by the pharmacist in accordance with this Section.

## 5. Administration of Vaccines

a. A collaborative drug therapy management agreement which includes the administration by a pharmacist of a patient specific order for administration of a disease specific vaccine shall include documentation of the pharmacist's authority to administer such medications, pursuant to §521 of the board's rules.

b. In addition to the requirements of this Section, the following information shall be included in any written protocol for any patient receiving a vaccination from a collaborating pharmacist:

i. the identity of the drug, dose, and route of administration;

ii. the date of the original order and the date of any authorized subsequent dose or administration;

iii. a statement the patient or patient's tutor, curator or legal guardian shall be provided the manufacturer's vaccine information statement with each dose;

iv. confirmation written policies and procedures for disposal of used or contaminated supplies shall be utilized;

v. a requirement for the pharmacist to immediately report any adverse event to the collaborating physician and such governmental entities as may be directed or required by the Louisiana Department of Health and Hospitals; and

vi. confirmation the physician shall be promptly available for consultation regarding contraindications and adverse reactions in said physician's patient.

c. This Section shall not prevent or restrict the Louisiana Department of Health and Hospitals, Office of Public Health, or any other governmental entity of this state from administering vaccines under the authority of other laws of this state.

6. Additional Refills. Whether or not and the extent to which a collaborating physician may authorize a collaborating pharmacist to dispense up to a single seven day supply of a single drug for a single patient utilized for disease specific drug therapy after all refills authorized for such physician's patient have been dispensed, shall be specifically included in the collaborative drug therapy management agreement with such pharmacist, as well as the written protocol applicable to a specific patient.

## 7. Reporting Obligations and Responsibilities

a. A pharmacist engaged in collaborative drug therapy management shall notify the board, in writing, within 10 days of the occurrence or discovery of:

i. the death of a patient which was, in the pharmacist's opinion, directly related to drug therapy management;

ii. complications or errors which are, in the pharmacist's opinion, directly related to drug therapy management;

iii. a pharmacist's termination of a collaborative drug therapy management agreement with a physician and applicable reasons;

iv. a physician's termination of a collaborative drug therapy management agreement with a pharmacist and applicable reasons;

v. a patient's election to withdraw from participation in collaborative drug therapy management and applicable reasons;

vi. his or a physician's failure or refusal to abide by the terms, conditions, or restrictions of a collaborative drug therapy management agreement or written protocol and applicable reasons;

vii. the pharmacist's retirement or withdrawal from active practice in this state or relocation to another state to engage in pharmacy practice; or

viii. the revocation, suspension, or other restriction imposed on a physician's license which would prohibit the physician from entering into a collaborative drug therapy management agreement.

b. A pharmacist engaged in collaborative drug therapy management shall comply with reasonable requests by the board for personal appearances or information relative to the functions, activities, and performance of a pharmacist or physician engaged in collaborative drug therapy management.

#### 8. Records

a. The following information shall be included in the pharmacy's record of a patient subject to collaborative drug therapy management:

i. the prescription or order implementing collaborative drug therapy management;

ii. the written protocol applicable to the patient evidencing documentation of annual review;

iii. documentation of all activities performed by the pharmacist;

iv. consultations and reports by and between the pharmacist and physician; and

v. documentation of the patient's informed consent to collaborative drug therapy management.

b. A pharmacist registered to engage in collaborative drug therapy management shall maintain and produce, upon inspection conducted by or at the request of a representative of the board, a copy of any or all collaborative drug therapy management agreements, amendments thereto, applicable written protocols and such other records or documentation as may be requested by the board to assess a pharmacist's compliance with requirements of this Section, the Pharmacy Practice Act, or other applicable board rules.

#### E. Sanctions

1. Action against Registration. For noncompliance with any of the provisions of this Section, the board may, in addition to or in lieu of administrative proceedings against a pharmacist's license, suspend or revoke a pharmacist's registration to engage in collaborative drug therapy management, or may impose such terms, conditions, or restrictions thereon as the board may deem necessary or appropriate.

2. Action against Pharmacist License. Any violation or failure to comply with the provisions of this Section shall be deemed a violation R.S. 37:1241.A.1, as well as a violation of any other applicable provision of R.S. 37:1241.A, providing cause for the board to take any of the actions permitted in R.S. 37:1241.A against the pharmacist's license.

3. Unauthorized Practice. Nothing in this Section shall be construed as authorizing a pharmacist to issue prescriptions, exercise independent medical judgment, render diagnoses, provide treatment, assume independent responsibility for patient care, or otherwise engage in the practice of medicine as defined in the Louisiana Medical Practice Act. Any person who engages in such activities, in the absence of medical licensure issued by the Louisiana State Board of Medical Examiners, shall be engaged in the unauthorized practice of medicine and subject to the penalties prescribed by the Louisiana Medical Practice Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1164(37)(b)(i).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1125 (June 2007).