Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 5. Pharmacists

Subchapter B. Professional Practice Procedures

§523. Collaborative ~~Drug Therapy Management~~ Practice

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* or *Drug Therapy Management* – that practice in which a pharmacist voluntarily agrees with a physician 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 patient specific written order set. 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 an order set, provided such tests do not require the pharmacist to interpret such testing or formulate a diagnosis; and~~

~~e. providing disease or condition specific patient education and counseling.~~

~~*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 the diseases or condition.~~

~~*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 procedures established by the Louisiana Prescription Monitoring Program Act, R.S. 40:1001-1014, as a drug with the potential for abuse.~~

~~*Pharmacist* – for purposes of this Section, an individual who has a current unrestricted license to practice pharmacy in this state duly licensed by the board, who is approved by the board to engage in collaborative practice for a specific disease or condition based on the pharmacist's training and experience.~~

~~*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 or device 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~~.

~~*Order Set* – 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 order set shall be signed by the physician and represents the physician orders for the collaborative drug therapy management to be provided to the patient.~~

Protocol – a guideline referenced in a collaborative practice agreement that outlines the processes for patient care services.

~~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 substance license, permit, or registration (state or federal);~~

~~iii. has had an application for pharmacist licensure rejected or denied; or~~

~~iv. 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.~~

~~a. 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 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 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. the nature of the collaborative drug therapy management activities contemplated, i.e., the disease or condition proposed for management;~~

~~iii. a description of the pharmacist's professional education that qualifies him to engage in collaborative drug therapy management activities described in the application;~~

~~iv. proof documented in a form satisfactory to the board that the pharmacist possesses the qualifications set forth in this Section; and~~

~~v. 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. 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.~~

~~b. 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.~~

~~c. 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.~~

~~d. 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.~~

~~e. 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.~~

~~1. 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 the pharmacist;~~

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

~~iv. notification to the board that the pharmacist 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 completing the application form supplied by 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 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~~ B. Standards of Practice

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

a. A pharmacist ~~registered with~~ holding an active and unrestricted license issued by the board ~~under this Section~~ may, independently or in conjunction with one or more similarly licensed pharmacists, engage in collaborative ~~drug therapy management~~ practice with ~~a physician~~ one or more practitioners in accordance with a ~~patient specific, drug specific, disease specific order set~~ collaborative practice agreement satisfying the requirements of this Section.

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

i. retain professional responsibility ~~to his patient for the management of their drug therapy~~ for his patient's treatment outcomes within the scope of his practice authority;

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

~~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 scheduled basis no less than every three months, a 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. This requirement may be met by entering the information in the patient's medical record; and~~

v. be available through direct ~~tele~~communication 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 pharmacist registered to engage in drug therapy management shall not allow another pharmacist not so registered or any other individual to exercise the authority conferred by such registration.~~

~~d. Collaborative drug therapy management shall only be utilized for disease specific drug therapy as defined in this Section.~~

~~e. 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 or condition specific order set based on a face-to-face visit with the patient;~~

~~ii. initiation or discontinuance of drug therapy by a pharmacist, except as specified in the order set;~~

~~iii. the management of controlled substances or drugs of concern; or~~

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

c. The collaborative practice agreement shall identify the:

i. collaborating pharmacist(s) and practitioner(s).

ii. patient care services intended to achieve optimal medication use and desired patient outcomes.

iii. protocol(s) to be used by the collaborators.

iv. appropriate mechanism(s) to initiate a therapeutic relationship with a patient.

2. ~~Informed~~ Patient Consent

a. A pharmacist shall not ~~engage in collaborative drug therapy management of~~ provide collaborative practice services to a patient without the patient's ~~written informed~~ consent as directed by the applicable state law.

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

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~~ provide the patient with information so that he understands the role of the pharmacist and practitioner in the collaborative relationship;

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~~ assure the patient understands he may decline to receive services from the pharmacist at the initial encounter or in the future without compromising his relationship with the practitioner; and

iii. provide~~d~~ 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~~ between the pharmacist(s) and the practitioner(s).

~~c. All services provided shall be performed in a setting which insures patient privacy and confidentiality.~~

3. ~~Order Sets~~ Initiation of Services

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

~~i. provided to the collaborating physician and pharmacist; and~~

~~ii. made part of the patient's pharmacy record.~~

~~b. A physician shall develop a patient specific order set for a particular patient or utilize a standard written protocol order set , incorporating what patient specific deviations, if any, the physician may deem necessary or appropriate for such patient. In either event, an order set 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 order set utilized for collaborative drug therapy management of a patient shall be reviewed annually by the collaborating physician, or more frequently as such physician deems necessary, to address patient needs and to insure compliance with the requirements of this Section. The physician's signature and date of review shall be noted on the order set and maintained by the pharmacist in accordance with this Section.~~

a. The mechanism to initiate a therapeutic relationship with a patient shall include the patient's consent to treatment and shall be recorded and archived for review consistent with all recordkeeping standards.

i. Protocols that anticipate the practitioner identifying the patient and personalizing the treatment plan may be initiated through a patient-specific order that references the protocol for the medical condition or drug therapy identified in the collaborative practice agreement.

ii. Protocols that anticipate the pharmacist initiating the therapeutic relationship with the patient should include a mechanism for referral of the patient to the appropriate practitioner within a specified time limit that affirms and supports the value of a medical home led by a practitioner.

~~4. Reporting Obligations and Responsibilities~~

~~a. A pharmacist engaged in collaborative drug therapy management shall report annually, as a condition to the renewal of his registration, whether or not and the extent to which the pharmacist is engaged in collaborative drug therapy management and such other information as the board may request.~~

~~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.~~

~~5. 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 order set applicable to the patient evidencing documentation of the physician's annual review;~~

~~iii. documentation of all activities performed by the pharmacist;~~

~~iv. consultations and status 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 order sets 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~~ C. 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 of R.S. 37:1241.A.1, as well as a violation of any other applicable provisions 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.~~

1. The failure of a pharmacist to comply with the provisions of this Section shall constitute unprofessional conduct and provide sufficient basis for the board to take any of the disciplinary actions identified in R.S. 37:1241(A).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:~~1164(37)(b)(i)~~ 1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1125 (June 2007), amended LR 39:3291 (December 2013), amended by the Department of Health, Board of Pharmacy, LR