

Chapter 74. Collaborative Drug Therapy Management

Subchapter A. General Provisions

§7401. Scope of Subchapter

A. The rules of this Chapter govern the registration and practice of physicians engaged in collaborative drug therapy management with pharmacists in this state.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1639 (August 2007).

§7403. Definitions

A. As used in this Chapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified.

Board—the Louisiana State Board of Medical Examiners, as constituted in the Medical Practice Act.

Collaborative Drug Therapy Advisory Committee or Advisory Committee—the Louisiana State Board of Medical Examiners' Collaborative Drug Therapy Advisory Committee, as constituted under §7417 of this Chapter.

Collaborative Drug Therapy Management Agreement or 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.

Collaborative Drug Therapy Management or 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 board under this Chapter, 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 Louisiana Board of Pharmacy;
- f. providing up to a single seven-day supply of a single drug, in accordance with §7433 of this Chapter, 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.

Controlled Substance - any substance defined, enumerated, or included in federal or state statute or regulations 21 C.F.R. 1308.11-.15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations or statute.

Disease Specific Drug Therapy - a specific drug(s) 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 and 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 legend drug.

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.

Legend Drug—for purposes of this Chapter, any drug bearing on the label of the manufacturer or distributor as required by the Food and Drug Administration, the statement "Caution: Federal law prohibits dispensing without a prescription" or "Rx Only." For purposes of this Chapter, legend drugs do not include controlled substances.

Medical Practice Act or the Act—R.S. 37:1261-92 as may be amended from time to time.

Medication—except in these rules where its use may indicate otherwise, is synonymous with *drug*, as defined herein.

Pharmacist—for purposes of this Chapter an individual who has a current, unrestricted license to practice pharmacy in this state duly issued by the Louisiana Board of Pharmacy and has completed a certificate program in the area of practice covered by a collaborative drug therapy management agreement approved by the Accreditation Council for Pharmacy Education, or the academic degree of Doctor of Pharmacy that provides training in the area of

practice covered by the agreement, or such other advanced training or program as may be recommended by the advisory committee and approved by the board.

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 board.

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/her patient.

Written Protocol—a written set of directives or instructions containing each of the components specified by §7429 of this Chapter 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1639 (August 2007).

Subchapter B. Prohibitions and Exceptions

§7405. Prohibitions and Exceptions

A. No physician shall engage in collaborative drug therapy management except in compliance with the rules of this Chapter.

B. This Chapter shall not apply to a physician's practice in a hospital licensed by the Louisiana Department of Health and Hospitals, provided the medication ordered or prescribed by the physician for in-patients of the hospital is managed in accordance with a written agreement approved by the members of the medical staff of the hospital.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1640 (August 2007).

Subchapter C. Registration

§7407. Eligibility for Registration

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

1. possess a current, unrestricted license to practice medicine issued by the board and not be the subject of a pending investigation or complaint by the board or by the medical licensing authority of any other state or jurisdiction;

2. be actively engaged in the clinical practice of medicine and the provision of patient care in this state in the particular field of medicine in which collaborative drug therapy management is to take place;

3. not be currently enrolled in a medical residency training program; and

4. not be employed by or serve as an independent contractor to a pharmacist, pharmacy, or pharmaceutical company, or be a party to any other or similar employment, contractual or financial relationship. The board may, in its discretion, grant an exception to this requirement on a case-by-case basis where it has been shown to its satisfaction that such relationship is structured so as to prohibit interference or intrusion into the physician's relationship with patients, the exercise of independent medical judgment and satisfaction of the obligations and responsibilities imposed by law or the board's rules on the physician.

B. A physician shall be deemed ineligible for registration of collaborative drug therapy management who:

1. does not possess the qualifications prescribed by Subsection A of this Section;

2. has voluntarily surrendered or had suspended, revoked or restricted, his/her controlled substances license, permit or registration, either state or federal;

3. has had a medical license suspended, revoked, placed on probation or restricted in any manner by the board or by the medical licensing authority of any other state or jurisdiction;

4. has had an application for medical licensure rejected or denied; or

5. 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. Upon the affirmative recommendation of the advisory committee the board may, in its discretion, waive the ineligibility restrictions of Paragraphs 7407.B.2-5 of this Section on a case-by-case basis where it has been shown to its satisfaction that the license, registration, permit, or participation in the health insurance program giving rise to ineligibility has been granted, reinstated or restored on an unrestricted basis, that following such action the individual has not been subject to further or additional disqualifying action and has demonstrated exemplary conduct or accomplishments meriting waiver consideration.

D. The board may deny registration to an otherwise eligible physician for any of the causes enumerated by R.S. 37:1285(A), or any other violation of the provisions of the Medical Practice Act or of the board's rules.

E. The burden of satisfying the board as to the eligibility of a physician for registration to engage in collaborative drug therapy management shall be upon the physician. A physician shall not be deemed to possess such qualifications

unless and until the physician demonstrates and evidences such qualifications in the manner prescribed by and to the satisfaction of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1640 (August 2007).

§7409. Registration Procedure

A. Application for registration to engage in collaborative drug therapy management shall be made upon forms supplied by the board.

B. Application forms and instructions may be obtained from the board's web site www.lsbme.louisiana.gov or upon contacting the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1640 (August 2007).

§7411. Original Application; Issuance of Registration

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

1. the physician's full name, license number, home address, e-mail address, emergency contact information, and the municipal post office address of each office or other location at which the applicant practices medicine in this state;

2. a description of the physician's professional background, specialty and the nature and scope of medical practice;

3. proof documented in a form satisfactory to the board that the physician possesses the qualifications set forth in this Subchapter;

4. a fully executed copy of a collaborative drug therapy management agreement that conforms to the requirements of §7427 of these rules;

5. confirmation that the physician shall only engage in collaborative drug therapy management in the particular field of medicine in which collaborative drug therapy management is to take place and in accordance with the rules and regulations adopted by the board; and

6. such other information and documentation as the board may require to evidence qualification for registration.

B. The board may reject or refuse to consider any application for registration that is not complete in every detail required by the board or a collaborative drug therapy management agreement that fails to comply with the minimum requirements specified by §7427 of this Chapter. The board may in its discretion require a more detailed or complete response to any request for information set forth in the application or the collaborative drug therapy management agreement as a condition to consideration.

C. A physician 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 physician's application, finds discrepancies in the application, or for other good cause as determined by the board.

D. Registration of authority to engage in collaborative drug therapy management shall not be effective until the physician receives notification of approval from the board. If all the qualifications, requirements and procedures of §§7407, 7409, and 7411 of this Subchapter are met to the satisfaction of the board, the board shall approve and register a physician to engage in collaborative drug therapy management.

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

F. Each registered physician is responsible for updating the board within 15 days in the event any of the information required and submitted in accordance with §§7407, 7409 and 7411 of this Subchapter changes after the physician has become registered to engage in collaborative drug therapy management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6), and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1640 (August 2007).

§7413. Notice of Intent to Collaborate

A. Notification of intent to engage in collaborative drug therapy management with a pharmacist, other than the pharmacist identified in the physician's original application, shall be filed with the board by a registered physician for each pharmacist with whom the physician intends to collaborate. Such notification shall be deemed given upon the physician's filing with the board, prior to initiating collaborative drug therapy management, a notice of intent to engage in collaborative drug therapy management on a form supplied by the board, along with a fully executed copy of a collaborative drug therapy management agreement with such pharmacist that conforms to the requirements of §7427 of these rules. Prior to engaging in collaborative drug therapy management with such pharmacist the physician shall have received confirmation and approval of notification of intent from the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1641 (August 2007).

§7415. Expiration of Registration; Renewal

A. A physician's registration to engage in collaborative drug therapy management with a pharmacist shall terminate and become void, null and of no effect upon the earlier of:

1. death of either the physician or a pharmacist;
2. loss of license of either the physician or pharmacist;
3. disciplinary action limiting the ability of either the physician or a pharmacist to enter into collaborative drug therapy management;
4. notification to the board that either the physician or pharmacist has withdrawn from collaborative drug therapy management;
5. a finding by the board of any of the causes that would render a physician ineligible for registration under this Subchapter; or
6. expiration of a physician's medical 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 physician's medical license unless renewed by a physician 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 physician's renewal application for medical 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1641 (August 2007).

Subchapter D. Collaborative Drug Therapy Advisory Committee

§7417. Constitution of Committee

A. To assist the board on matters relative to collaborative drug therapy management, a Collaborative Drug Therapy Management Advisory Committee is hereby constituted, to be composed and appointed, to have such functions, and to discharge such duties and responsibilities as hereinafter provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1641 (August 2007).

§7419. Composition; Appointment

A. The advisory committee shall be composed of seven members, consisting of four physicians and three pharmacists. These members shall include: one physician designated by the Louisiana State University Health Sciences Center School of Medicine in New Orleans; one physician designated by the Louisiana State University Health Sciences Center School of Medicine in Shreveport; one physician designated by the Tulane University Health Sciences Center School of Medicine; one physician designated by the Louisiana State Medical Society; one pharmacist who holds the academic degree of Doctor of Pharmacy designated by the Xavier University of Louisiana College of Pharmacy; one pharmacist who holds the academic degree of Doctor of Pharmacy designated by the University of Louisiana at Monroe School of Pharmacy; and one pharmacist designated by the Louisiana Board of Pharmacy. The president of the Louisiana State Board of Medical Examiners or his/her designee may sit on the committee in an ex officio capacity.

B. To be eligible for appointment to the advisory committee each individual shall have maintained residency and practiced their profession in the state of Louisiana for not less than one year, hold the qualifications prescribed by this Chapter for those of their respective professions who may wish to engage in collaborative drug therapy management, and possess education, particular experience, advanced training or other qualifications that the board may deem to be of value to the advisory committee in the discharge of its duties and responsibilities.

C. Each member of the advisory committee shall be appointed by the board from among a list of one or more qualified nominees for each position submitted to the board. Accompanying each nominee shall be a personal resume or curriculum vitae for the individual. In the event a designating entity does not submit nominees within 60 days of the board's request the position or vacancy may be filled by a physician or pharmacist designated by the board. Each member of the advisory committee shall serve for a term of three years or until a successor is appointed and shall be eligible for reappointment. With the exception of the member designated by the Louisiana Board of Pharmacy, who shall serve at the pleasure of that board, all members of the advisory committee shall serve and be subject to removal at any time at the pleasure of the board. Members appointed to fill a vacancy occurring other than by expiration of the designated term shall serve for the unexpired term. Appointments to the advisory committee shall be effective when made with respect to appointments for unexpired terms and otherwise shall be effective as of the first day of the year following the date of appointment.

D. The advisory committee shall meet not less than twice each calendar year, or more frequently as may be deemed necessary or appropriate by a quorum of the advisory committee or by the board. The presence of four members shall constitute a quorum. The advisory committee shall elect from among its members a chairperson, a vice-chairperson and a secretary. The chair or in the absence or

unavailability of the chair the vice-chair, shall call, designate the date, time and place of, and preside at meetings of the advisory committee. The secretary shall record or cause to be recorded, accurate and complete written minutes of all meetings of the advisory committee and shall cause copies of the same to be provided to the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1641 (August 2007).

§7421. Duties and Responsibilities

A. The advisory committee is authorized by the board to assist by:

1. reviewing applications for physician registration and notifications of intent to engage in collaborative drug therapy management and collaborative drug therapy management agreements, to insure compliance with the requirements of this Chapter;

2. identifying disease specific conditions for which there are generally accepted standards of care that are amenable to collaborative drug therapy management. The committee shall periodically, but not less frequently than annually, provide the board with recommendations relative to additional diseases, conditions, vaccines, and categories of drugs that may be appropriate for collaborative drug therapy management;

3. providing advice and recommendations to the board respecting the modification, amendment, and supplementation of its rules concerning physicians who engage in collaborative drug therapy management;

4. serving as a liaison between and among the board, physicians and pharmacists who engage in collaborative drug therapy management; and

5. identifying and recommending to the board acceptable certificate programs and other advanced training or programs in the areas of practice covered by collaborative drug therapy management agreements.

B. In discharging the functions authorized under this Section the advisory committee and the individual members thereof shall, when acting within the scope of such authority, be deemed agents of the board. All information obtained by the advisory committee members pursuant to this Section shall be considered confidential. Advisory committee members are prohibited from communication, disclosing, or in any way releasing to anyone any information or documents obtained when acting as agents of the board without first obtaining the written authorization of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1642 (August 2007).

Subchapter E. Standards of Practice

§7423. Authority, Responsibility and Limitations of Collaborative Drug Therapy Management

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

1. to the extent authorized by a collaborative drug therapy management agreement that has been filed with and approved by the board; and

2. in accordance with a patient specific, drug specific, disease specific written protocol, satisfying the requirements of §7429 of this Chapter.

B. A physician engaged in collaborative drug therapy management shall:

1. retain professional responsibility to his/her patients for the management of their drug therapy;

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

3. be geographically located so that the physician, or a back-up physician as provided in §7427.D of this Chapter, is able to be physically present daily to provide medical care to a patient subject to collaborative drug therapy management;

4. receive 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

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

C. A physician's registration to engage in collaborative drug therapy management with a pharmacist is personal to the physician. A registered physician shall not allow another physician or any other individual to exercise the authority conferred by such registration. A registered physician shall not engage in collaborative drug therapy management with a non-pharmacist or with any pharmacist who is not a party to the physician'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 §7403 of this Chapter. 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 in accordance with 7403. Definitions. *Disease Specific Drug Therapy* and §7421 of this Chapter.

E. A physician shall only engage in collaborative drug therapy management of anti-coagulant therapy with a pharmacist who holds the academic degree of Doctor of Pharmacy, which degree provided training in the area of practice covered by the agreement. The board may, in its discretion, grant an exception to this limitation on a case-by-

case basis and permit a physician to engage in anti-coagulant drug therapy management with a pharmacist who does not possess the academic degree required by this Subsection 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:

1. any patient of the physician for whom such physician has not prepared a patient specific, drug specific, disease specific written protocol;
2. drug therapy management of more than one specific disease or condition. Administration of a vaccine or smoking cessation therapy are excepted from this provision;
3. drug therapy management of any patient by more than one registered physician and one pharmacist;
4. any patient under 18 years of age. Administration of a vaccine or smoking cessation therapy are excepted from this provision;
5. pregnant or nursing mothers;
6. initiation or discontinuance of drug therapy by a pharmacist, except as specified in the written protocol;
7. the management of controlled substances or drugs of concern; or
8. substitution of a drug prescribed by a physician without the explicit written consent of such physician.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1642 (August 2007).

§7425. Informed Consent

A. A physician 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 collaborative drug therapy management shall be:

1. 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 physician and pharmacist;
2. informed that he or she may decline to participate in a collaborative drug therapy management practice and may withdraw at any time without terminating the physician-patient relationship; and
3. provided written disclosure of any contractual or financial arrangement with any other party that may impact one of the party's decisions 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 that insures patient privacy and confidentiality.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1643 (August 2007).

§7427. Collaborative Drug Therapy Management Agreement

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

1. the name, professional license number, address(es), telephone/cell number, e-mail address and emergency contact information for the physician and pharmacist and the date of signing and termination of the agreement;
2. a description of the manner and circumstances under which the physician and pharmacist will engage in collaborative drug therapy management;
3. the condition or disease to be managed;
4. the disease specific drug(s) to be utilized for such condition or disease;
5. the drug therapy management activities, as defined in §7403 of this Chapter, the physician authorizes the pharmacist to perform;
6. the procedure to be followed by the parties for drug therapy management and a plan of accountability that defines the respective responsibilities of the physician and pharmacist;
7. a plan for reporting and documenting drug therapy management activities in the medical and pharmacy records and schedule by which such are to take place. A physician shall insure that the pharmacist submits a report at least every 30 days, or more frequently if warranted by clinical conditions, to the physician regarding the status of a patient's collaborative drug therapy management, which report shall be noted in and made part of the physician's record on the patient;
8. a plan for record keeping, record sharing and record storage. The agreement shall acknowledge that all collaborative drug therapy management records shall be treated as and governed by the laws applicable to physician medical records;
9. acknowledgement that 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 physician and pharmacist are absent from the practice setting; and
10. the procedure and schedule for reviewing and assessing the quality of care provided to patients 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(s) directly related to the disease specific drug therapy being managed under written protocol, the agreement shall identify the specific test(s) and describe the plan for securing such testing.

C. The agreement shall affirm that:

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

2. 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

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

D. The agreement may include the identity of a single back-up physician possessing the qualifications for collaborative drug therapy management prescribed by this Chapter, who will serve in the absence of the registered physician to the agreement. The identifying information specified by Paragraph 7427.A.1 of this Section shall be provided for such physician, along with an acknowledgment of responsibility to adhere to the same obligations and commitments imposed upon the registered physician to the agreement, as evidenced by a dated signature.

E. An agreement is valid for a period not to exceed one year. A physician shall insure that a collaborative drug therapy management agreement is annually reviewed, updated as appropriate, signed by the physician and pharmacist and submitted to the board for review and approval of any substantive changes.

F. Each registered physician is responsible for updating the board within 15 days in the event any of the information required and submitted in accordance with this Section changes after the board has approved the agreement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1643 (August 2007).

§7429. 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:

1. provided to the collaborating pharmacist;
2. made part of the patient's medical record; and
3. appended by the physician to the collaborative drug therapy management agreement with the pharmacist and maintained in a separate file at the practice site listed on the physician'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:

1. the physician, the pharmacist and telephone number and other contact information for each;
2. the patient's name, address, gender, date of birth, and telephone number;
3. the disease or condition to be managed;
4. the disease specific drug(s) to be utilized;
5. the type and extent of drug therapy management the physician authorizes the pharmacist to perform;
6. the specific responsibilities of the physician and pharmacist;
7. the procedures, criteria or plan the pharmacist is required to follow in connection with drug therapy management;
8. the specific laboratory test(s), if any, that are directly related to drug therapy management that the physician authorizes the pharmacist to order and evaluate;
9. the reporting and documentation requirements of the physician and pharmacist respecting the patient and schedule by which such are to take place;
10. the conditions and events upon which the physician and pharmacist are required to notify one another; and
11. procedures to accommodate immediate consultation by telephone or direct telecommunication with or between the physician, pharmacist and/or the patient.

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1644 (August 2007).

§7431. Administration of Vaccines

A. A physician who engages in collaborative drug therapy management with a pharmacist that includes administration of a patient specific order for administration of a disease specific vaccine:

1. shall:
 - a. include such authority in the collaborative drug therapy management agreement with such pharmacist that has been filed with the board; and

b. annex documentation to the collaborative drug therapy management agreement evidencing such pharmacist is currently authorized by the Louisiana Board of Pharmacy to administer medication and confirming that such pharmacist shall in every instance adhere to the requirements specified by Section 521 of the Louisiana Pharmacy Board's rules relative to administration of vaccines.

2. In addition to the requirements of Section 7429 and Subsection A of this Section, a physician shall include within the written protocol for any patient of such physician to receive a vaccine:

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

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

c. a statement that the patient or patient's legal guardian shall be provided the manufacturer's vaccine information statement with each dose;

d. confirm that written policies and procedures for disposal of used or contaminated supplies shall be utilized;

e. require 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

f. confirm that the physician shall be promptly available for consultation regarding contraindications and adverse reactions to such physician's patient.

B. This Chapter 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1644 (August 2007).

§7433. Additional Refills

A. Whether or not and the extent to which a physician may authorize a 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1645 (August 2007).

§7435. Reporting Obligations and Responsibilities

A. A physician engaged in collaborative drug therapy management shall:

1. within 15 days of the occurrence or discovery notify the board in writing of:

a. the death of a patient that was, in the physician's opinion, directly related to drug therapy management;

b. complications or errors that are, in the physician's opinion, directly related to drug therapy management;

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

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

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

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

g. the physician's retirement or withdrawal from active clinical practice in this state or relocation to another state to engage in practice; or

h. the revocation, suspension or other restriction imposed on a pharmacist's license that would prohibit the pharmacist from entering into a collaborative drug therapy management agreement;

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1645 (August 2007).

§7437. Records

A. Included with a physician's medical record on a patient subject to collaborative drug therapy management shall be a copy of:

1. the prescription or order implementing drug therapy management;

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

3. documentation of all activities performed by the physician and pharmacist;

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

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

B. A physician registered to engage in 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 agreement(s), amendments thereto, applicable written protocols and such other records or documentation as may be requested by the board to assess a physician's compliance with the requirements of this Chapter, the Act or other applicable rules of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1645 (August 2007).

Subchapter F. Sanctions

§7439. Action against Medical License

A. Any violation or failure to comply with the provisions of this Chapter shall be deemed unprofessional conduct and conduct in contravention of the board's rules, in violation of R.S. 37:1285(A)(13) and (30), respectively, as well as violation of any other applicable provision of R.S. 37:1285(A), providing cause for the board to suspend, revoke, refuse to issue or impose probationary or other restrictions on any license to practice medicine in Louisiana held or applied for by a physician culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6), 1285, and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1645 (August 2007).

§7441. Action against Registration

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6), 1285, and 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1646 (August 2007).

§7443. Unauthorized Practice

A. Nothing in this Chapter 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 Medical Practice Act. Any person who engages in such activities, in the absence of medical licensure issued by the board, shall be engaged in the unauthorized practice of medicine and subject to the penalties prescribed by the Medical Practice Act.

B. Any physician who associates with or assists an unlicensed person engage in the practice of medicine shall

be deemed to be in violation of R.S. 37:1285(A)(18), providing cause for the board to suspend, revoke, refuse to issue or impose probationary or other restrictions on any license to practice medicine in Louisiana held or applied for by a physician culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6), 1271, 1285, 1286, 1290, and R.S. 37:1164(37).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 33:1646 (August 2007).

