Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 1. Introduction

§101. Preamble

A. Pursuant to the authority granted by R.S. 37:1182, and in the interest of promoting the public health, safety, and welfare, the following rules and regulations are hereby adopted by the Louisiana Board of Pharmacy (board).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2075 (October 2003), effective January 1, 2004.

§103. Pharmacy Board Organization

A. Board Officers
   1. President. The president shall preside at all board meetings.
   2. Vice-Presidents. In the absence of the president, the vice-presidents shall preside in descending order at all board meetings.
   3. Secretary. The secretary shall conduct the nomination procedure for board candidates and report the results of the balloting to the governor for his appointments.

B. Election
   1. General Election. The board shall annually elect officers from its membership.
   2. Special Election. The president may call a special election of the board to fill vacancies of elected officers.

C. Officers' Terms. Officers elected by the board shall serve one-year terms and their terms shall end upon the election of their successors. An officer elected to a vacant position shall serve for the remainder of that term, at which time an election shall occur commensurate with the annual election.

D. Per Diem. A per diem, as authorized by R.S. 37:1178, is defined as compensation to be received by a board member for each day of service while attending regular or called board meetings, while attending to official business of the board, or while attending a board related or board sanctioned conference, including travel days for members to and from these meetings, conferences, and related business. This per diem shall not serve as reimbursement for meals, lodging, and other expenses incurred as a result of these meetings, conferences, and related business.

E. Board Budget. The board is a self-sustaining body that shall generate sufficient revenues funded by fees, appropriations, and/or assessments in order to maintain efficient operations.
   1. Administrative Costs. The board may assess administrative costs as it deems necessary to facilitate the proper implementation of its rules and regulations.
   2. Annual Operating Budget. The board has the responsibility to perfect an annual operating budget.
   3. Annual Capital Budget. The board has the responsibility to establish a capital budget, when applicable.

F. Executive Director. The executive director shall carry out functions of the board relative to its statutory requirements and other duties as defined by the board. With the board's approval, the executive director serves as the appointing authority and may appoint additional employees for professional, clerical, and special duties necessary to carry out the board's functions and may establish standards for the conduct of employees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2075 (October 2003), effective January 1, 2004.

§105. Board Procedures

A. All board procedures and operations shall adhere to the Administrative Procedure Act, R.S. 49:950 et seq., the Open Meetings Law, R.S. 42:4.1 et seq., and the Public Records Act, R.S. 44:1 et seq.

B. Order. Robert's Rules of Order shall govern all proceedings unless otherwise provided.

C. Public Comments. A public comment period shall be held during each board meeting.

1. Persons desiring to present public comments shall notify the board chairman or executive director no later than the beginning of the meeting. However, to assure that an opportunity is afforded to all persons who desire to make public comments, the chairman shall inquire at the beginning of the meeting if there are additional persons who wish to comment. The chairman shall allot the time available for the public comments in an equitable manner among those persons desiring to comment, limiting each person to a maximum of three minutes, with the total comment period not to exceed thirty minutes. Each person making public comments shall identify himself and the group, organization, company, or entity he represents, if any.
2. Unless otherwise provided by law, public comment is not part of the evidentiary record of a hearing or case unless sworn, subject to cross-examination, offered by a party as relevant testimony, and received in accordance with the Administrative Procedure Act, R.S. 49:950 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

§107. Board Committees and Subcommittees

A. Board committees are working bodies created by the board comprising members appointed or removed by the president to address and deliberate specific pharmacy matters referred by the board for specified periods consisting of the following:

1. Standing Committees. Standing committees are permanent bodies and are created by the board comprising members appointed by the president with the duty to address and deliberate specific subject matters referred by the board.
2. Special Committees. Special committees are appointed by the president for a particular period to address or deliberate special matters.
3. Board Subcommittees. Board subcommittees are created by the board comprising members and ex-officio non-voting members appointed by the president that are ancillary to a standing or special committee to address or deliberate a limited committee subject matter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

§109. Standing Board Committees

A. Executive Committee. The executive committee, comprised of the president, vice-presidents, and secretary shall function to address interim administrative board matters that require immediate attention between regularly scheduled board meetings.

B. Regulation Revision Committee. The regulation revision committee, consisting of at least three board members appointed at the discretion of the president, shall function to preliminarily draft rules, regulations, and policies to be considered by the full board for promulgation and/or resolution or order.

C. Reciprocity Committee. The reciprocity committee, consisting of at least three board members appointed at the discretion of the president, shall function to document the qualifications, compliance, and credentials of reciprocity candidates.

D. Impairment Committee. The impairment committee, consisting of at least three board members appointed at the discretion of the president, shall function to study, recognize, address the need to identify, and monitor the recovery of impaired persons in order to protect the public and the practitioner. Additionally, the impairment committee shall function to investigate, review, and interview impaired or allegedly impaired persons practicing or assisting in the practice of pharmacy and tender findings and recommendations to the board.

E. Violations Committee. The violations committee shall consist of at least three board members appointed at the discretion of the president. Board-designated staff shall preliminarily determine the disposition of complaints and alleged offenses. Thereafter, the violations committee shall function to

receive complaints, receive staffs' reports, and evaluate and review findings. The disposition of alleged offenses shall be determined by conducting an informal inquiry conference, an interlocutory hearing, and/or referring the matter to special counsel for formal hearing by the full board.

F. Reinstatement Committee. The reinstatement committee, consisting of at least three board members appointed at the discretion of the president, shall function to receive complaints, receive staffs' reports, evaluate and review findings, interview applicants, deliberate, and tender recommendations to the full board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

§111. Official Journal

A. The official journal of the board is the *Louisiana Board of Pharmacy Newsletter*. The newsletter may be used in administrative hearings as proof of notification to pharmacists, interns, pharmacy technicians, pharmacy technician trainees, and holders of pharmacy permits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 3. Board Hearings

§301. Board Hearing Procedures and Jurisdiction

A. Person. The board has jurisdictional authority over the person practicing pharmacy, assisting in the practice of pharmacy, operating a pharmacy, or otherwise licensed, registered, certified, or permitted by the board. A person is as defined in R.S. 37:1164(33) of the Pharmacy Practice Act.

B. Subject Matter. The board has jurisdiction over any subject matter related to the practice of pharmacy or any other matter regarding the dispensing or selling of prescription drugs in a safe manner so as not to endanger the public health, safety, or welfare.

C. Board Authority. The board has authority to adopt rules pursuant to the Pharmacy Practice Act, R.S. 37:1161 et seq., and the Administrative Procedure Act, R.S. 49:950 et seq., regarding due process disciplinary hearings.

D. Venue. A due process hearing shall convene in a designated Louisiana parish at a regularly called board meeting.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§303. Summons

A. A summons shall represent a complaint of an alleged violation directed to a respondent.

B. Hearing Notice. The board shall initiate a hearing by issuing a notice summons. The notice summons shall be forwarded to the respondent commanding his presence to appear before the board for a due process hearing setting forth the following:

1. Name. The notice shall include the respondent's name and address.
2. Time. The notice shall state the designated time, date, and place.
3. Allegation. The notice shall recite the alleged violation(s) establishing a cause of action and the nature of the hearing.
4. Authority. The notice shall make references to specific board, state, or federal statutes, regulations, rules, policies, or code of ethics involved in the alleged violation(s).
5. Citation. The notice shall cite legal or jurisdictional authority constituting an alleged violation(s).
6. Documents. The notice may include supporting documents, reports, and/or other relevant material.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§305. Service

A. Method. Service of a summons shall be made either by regular, registered, or certified mail, with a return receipt requested, or board or court designated process servers confected by tendering the summons to the respondent personally or domiciliary at the last known address.

B. Time. Service shall be made at least thirty days prior to the date of the hearing as per R.S. 37:1245.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1245.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§307. Default Proceedings

A. The board may proceed with a hearing in the event the respondent fails to appear after due notice was perfected or a diligent effort had been made to perfect service on the respondent at the last known address of record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§309. Joinder

A. Several complaints may be joined or incorporated and the respondents may be joined in the same or similar complaints based on the same or similar acts or transactions that are connected in a common plan or scheme.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§311. Consolidation

A. Hearings may be held jointly to assure a fair due process hearing. Any alleged violations may be consolidated for an administrative hearing of respondents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§313. Severance

A. A severance of complaints is permitted when a fair due process hearing will not be satisfied. Otherwise, complaints may be heard jointly.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

§315. Motions

A. Hearing Motions. Motions are directed to the board or presiding officer for particular relief or action before, during, or after a hearing and shall be in writing when applicable, and allege specifically the grounds upon which the relief is based, and filed with the board five days before hearing or within ten days post-hearing or timely filed during the hearing. At an appropriate time to be decided by the hearing officer, oral or written motions may be directed to the presiding hearing officer during a hearing. Hearing motions are directed to the presiding hearing officer and disposed of appropriately.

B. Continuance Motions.
   1. Postponement Motions. The board may grant or deny a continuance based upon critical or extenuating circumstances that could jeopardize a fair and expeditious due process hearing.
   2. Time. Continuance motions shall be filed in writing at least five days prior to the scheduled hearing with specific grounds for postponement. This requirement may be waived by the board under emergency circumstances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§317. Recusation

A. A board member or special counsel may be recused by one's own motion because of an inability to contribute to a fair and impartial hearing or may be recused by a majority vote of the board members present based on the following grounds:
   1. Prejudicial or personal interest in a case that might prevent one from participating in an impartial hearing.

2. The board may recuse the presiding administrative hearing officer on his own motion or he may be disqualified based upon his own inability to contribute to or conduct an impartial hearing by the respondent filing an affidavit of specific grounds at least five days prior to the scheduled hearing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§319. Sequestration

A. Upon request by either respondent or special counsel or by direction of the hearing officer, witnesses shall be sequestered and not allowed in the hearing chambers or permitted to discuss their testimony with other witnesses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§321. Sanction Guidelines

A. The sanctions imposed by the board pursuant to R.S. 37:1241 of the Pharmacy Practice Act shall be based on the following guidelines:
   1. Nature. The nature or seriousness of the violation.
   2. Degree. The degree of culpability, knowledge and/or intent, or the responsibility to have knowledge.
   3. Scope. The scope of circumstances involved.
   4. Demeanor. Honesty and truthfulness of respondent.
   5. History. History of prior offenses.
   6. Sanctions. Prior sanctions.
   7. Cooperation. Willingness of respondent to comply with applicable laws and regulations and avoid future violations.
   8. Sufficiency. Sanctions are sufficient to remedy the problem.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§323. Administrative Investigation

A. Upon the receipt of a written complaint, board staff shall initiate and conduct an investigation.
   1. Grounds. The investigative report shall be reviewed by board-designated staff and forwarded to the violations committee or legal counsel to determine sufficient grounds for proceeding either informally or formally.
   2. The report shall include:
      a. respondent's name and address; and
      b. a concise statement of facts and circumstances indicating the basis of the routine or specific complaint or cause of action; and
      c. supporting documents and/or materials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§325. Violations Committee

A. Purpose. Board-designated staff shall receive reports and complaints and review and evaluate findings to determine the nature and disposition of the alleged violation(s). The alleged violation(s) may then be directed to:
   1. violations committee for informal hearing;
   2. violations committee for interlocutory hearing; and/or
   3. special counsel for institution of a formal administrative hearing.

B. Guidelines. If determined appropriate by board-designated staff, the violations committee shall receive and review complaints and determine the disposition of the pending matters based on the following:
    1. Seriousness. The seriousness of the alleged offense.
    2. Degree. The extent of the alleged violations.
    3. History. The history of prior violations.
    4. Record. Prior sanctions.
    5. Cooperation. Willingness to obey the prescribed laws and regulations.
    6. Deterrent. Consider the sanctions as a deterrent to future violations.
    7. Remedy. The sanctions are sufficient to remedy the problem.

C. Informal Hearings. The violations committee may conduct an informal non-adversarial hearing with the respondent properly noticed of the inquiry regarding the issues to be discussed. The committee shall receive information and deliberate as to a cause of action regarding a potential violation. The committee may recommend a course of action to the full board or dismiss the allegations by an affirmative majority vote of the committee. Should the violations committee recommend a course of action to the full board, the following shall apply:
    1. Disclosure. Respondent's testimony or the work product from the informal hearing of any staff or committee member may not be introduced at any subsequent formal hearing.
    2. Recusal. Violations committee members shall not be permitted to participate in subsequent formal board hearings pertaining to complaints or alleged violations heard by the violations committee, unless respondent allows otherwise.

D. Interlocutory Hearings. By interlocutory (or summary) hearing, the violations committee may summarily suspend a license, permit, certification, and/or registration prior to a formal administrative board hearing wherein, based upon the committee's judgment and reflected by adequate evidence and an affirmative majority decision, a person poses a danger to the public's health, safety, and welfare, and the danger requires emergency action.
    1. Summons Notice. A summary proceeding summons notice shall be served at least five days before the scheduled hearing to afford the respondent an opportunity to be heard with respect to a potential summary suspension action. The notice shall contain a time, place, nature, and the grounds asserted relative to the alleged conduct warranting summary suspension.
    2. Burden of Proof. Legal counsel shall have the burden of proof to support the contention that the public's health, safety, or welfare is in danger and requires summary or emergency action.
    3. Evidence. The respondent shall have the right to appear personally and/or be represented by counsel to submit affidavits, documentary evidence, or testimony in response to the cause of action asserted as the basis for the summary suspension.
    4. Decision. The committee shall determine whether to grant or deny the summary suspension based upon adequate evidence with an affirmative majority vote substantiated by finding(s) of fact and conclusion(s) of law that the public's health, safety, or welfare is in danger and requires emergency or summary action.
    5. Report. The committee shall submit their findings and interlocutory decree to the board when rendered.
    6. Suspensive Duration. The summary suspension decree shall be followed by a formal administrative hearing within thirty days from receipt of notice by the respondent.

E. Probation Violation Hearings. Probation violation proceedings shall be initiated upon receipt of information indicating that a respondent is in violation of any of the terms or conditions of his probation.
    1. Review. Board-designated staff shall receive and review the compliance officer's report and then determine whether a probation violation proceeding is warranted. Should a probation violation hearing be determined warranted, the violations committee shall proceed by interlocutory hearing or informal hearing as deemed appropriate.
    2. Notice. Notice shall be afforded the respondent of the allegation(s) forming the basis of the alleged violation status, and the time and place of the appropriate hearing to be conducted.
    3. Disposition. Disposition of the hearing shall be according to the appropriate procedures to informal hearings or interlocutory hearings.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

§327. Impairment Committee

A. Impairment – Impairment means a condition that causes an infringement on the ability of an individual to practice, or assist in the practice, of pharmacy sufficient to pose a danger to the public. Impairment may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.

B. The impairment committee shall have the following responsibilities:
   1. Supervise the Practitioner Recovery Program.
   2. Recommend for board consideration any addictionists or other professionals utilized by the program.
   3. Recommend for board consideration any action for reinstatement of recovering persons.
   4. Any other related responsibilities deemed appropriate by the board.

C. Practitioner Recovery Program. The board may establish and maintain a recovery program to assist impaired persons through the recovery process so that they may safely return to practice. The board may utilize the services of outside agencies to assist in the recovery of the impaired person.

D. Informal Hearing.
   1. The board may convene an informal administrative hearing to identify an impaired person and to take appropriate action. The board may require the appearance of any persons deemed necessary to properly conduct an informal hearing. This process shall be conducted by the impairment committee chairman or any other member(s) of the board or staff as the president deems necessary.
   2. Any knowledge acquired by any board member or staff in identifying and assisting an allegedly impaired person shall not automatically be grounds for recusal at any later hearing on that same matter.
   3. An impaired or allegedly impaired person may enter into a preliminary consent agreement that shall include a mandatory surrender of that person's license, permit, certification, or registration, which shall be delivered to the board office and shall effectively prohibit that person from practicing, or assisting in the practice of, pharmacy. Such person shall agree to enter into an approved treatment and monitoring program as determined by the board. This consent agreement shall not restrain the board from conducting violations proceedings in the matter as it deems necessary.
   4. The impairment committee may make recommendations to the full board and/or the violations committee as it deems appropriate on an impaired or allegedly impaired person.

E. Impaired Reinstatement. An application for reinstatement of an impaired person shall be filed with the impairment committee for consideration and recommendation to the violations committee and/or the full board.
   1. An impaired person may petition the board for reinstatement of his license, permit, certification, or registration, provided he has:
      a. documented proof from an attending physician that he has successfully completed an alcohol or substance abuse recovery program, and
      b. a current post-treatment evaluation from a board-approved addictionist, and
      c. successfully completed any requirements the board deems necessary with respect to the particular type of impairment.
      d. The impairment committee may waive the above requirements for impairments not related to alcohol or substance abuse.
   2. After the above stipulations have been met, the person applying for reinstatement may be scheduled for an interview with the impairment committee for consideration of any recommendation to the reinstatement committee and/or the full board.
   3. Upon reinstatement, the board may place the reinstated person on probation for a specified length of time and may assign conditions of the probation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2079 (October 2003), effective January 1, 2004.

§329. Formal Hearing

A. Authority. The board shall provide a formal administrative hearing pertaining to the proprietary rights or privilege to practice pharmacy, or operate a pharmacy, or hold a certificate or registration, in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., with authority to take disciplinary action pursuant to R.S. 37:1241 of the Pharmacy Practice Act.

B. Ex-Parte Communication. Once a formal hearing has been initiated and notice served, board members participating in the decision process shall not communicate with a respondent or a respondent's attorney concerning any issue of fact or law involved in the formal hearing.

C. Notice. A formal disciplinary public proceeding may be initiated upon proper notice to a respondent and held at a designated time and place based upon the following grounds:

1. violation – sufficient evidence or a serious complaint of an alleged violation to require a formal hearing shall be directed to legal or special counsel for administrative prosecution to justify a formal hearing; or
2. failure to respond – a failure by the respondent to respond to the violations committee informal inquiry; or
3. irresolvable issues – a violations committee informal hearing fails to resolve all issues and requires further formal action; or
4. irreconcilable issues – an interlocutory hearing fails to resolve all pertinent pending issues thus requiring further formal action, or
5. reaffirmation – reaffirmation of an interlocutory decree.
6. requirement – a formal administrative hearing requirement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2080 (October 2003), effective January 1, 2004.

§331. Formal Hearing Procedures

A. Hearing Officers.

1. Administrative Hearing Officer. The presiding hearing officer may be the board president, a vice-president, or other individual appointed by the president or his successor. The hearing officer has the responsibility to conduct a fair and impartial proceeding with the administrative duty and authority to:
    a. convene an administrative board hearing;
    b. rule on motions and procedural questions arising during the hearing such as objections or admissibility of evidence or examination of witnesses;
    c. issue or direct staff to issue subpoenas;
    d. declare recess;
    e. maintain order;
    f. enforce a standard of conduct to insure a fair and orderly hearing;
    g. remove disruptive person(s) from a hearing.
2. Oaths. The presiding hearing officer, executive director, or other board designee may administer oaths.

B. Administrative Jury. The board, comprised of a quorum of members, shall serve as an administrative jury to hear and determine the disposition of the pending matter based on the finding(s) of fact and conclusion(s) of law by receiving evidence and reaching a decision and/or ordering sanctions with an affirmative majority record vote of board members participating in the decision process.

C. Administrative Hearing Clerk. The board's executive director shall serve as the administrative hearing clerk and shall maintain administrative hearing records.

D. Administrative Prosecutor. The legal or special counsel shall prosecute the pending matter and bear the burden of proof to be presented to the board.

E. Administrative Reporting. The board-designated stenographer shall record all testimony dictated and evidence received at the hearing. The utilization of recording equipment may be employed.

F. Hearing Order.

1. Docket. Contested matters shall be identified by reference docket number and caption title. The administrative hearing clerk or other staff or board member designated by the presiding hearing officer shall announce the docket and identify persons present or absent in the hearing chambers.
2. Complaint. The complaint may be read at an open hearing unless waived by the respondent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2080 (October 2003), effective January 1, 2004.

§333. Pre-hearing Conference

A. Respondents and/or their legal counsel in matters pending before the board may be directed by the presiding administrative hearing officer to appear at a pre-hearing conference to consider the simplification of the issues, admission of facts, or stipulations to documents which may avoid unnecessary proof and such other items as may aid in the disposition of the matter(s) pending.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§335. Consent Agreements

A. Respondents may enter into consent agreements with the board on any matter pending before the board. A consent agreement is not final until the board approves the consent agreement by majority vote of the administrative jury. If the consent agreement is rejected in full or part, the matter shall be heard at the next regularly scheduled board hearing. However, nothing herein shall limit the board from modifying a consent agreement, with respondent's approval, to include less severe sanctions than those originally agreed to in a pending consent agreement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§337. Opening Statement

A. An opening statement by legal or special counsel may present a brief position comment with an outline of evidence to be offered. Respondent or respondent's legal counsel may present an opening defense position statement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§339. Evidence

A. Testimony Received. Testimony shall be received under oath administered by the presiding hearing officer, the executive director, or other staff or board member designated by the hearing officer.
B. Evidence Introduction. All parties shall be afforded an opportunity to present evidence on all issues of fact and argue on all issues of law and respond by direct testimony, followed with cross examination as may be required for a full and true disclosure of the facts. The direct presentation of evidence shall be introduced by the legal or special counsel and shall be followed by the respondent in proper person or by legal counsel by direct and/or cross-examination and/or rebuttal.
C. Examination. Witnesses may be directly examined and cross-examined. Additionally, witnesses and/or respondents may be questioned during an administrative hearing by members of the administrative jury on matters for clarification.
D. Rule Interpretation. Liberal rules of evidence shall be employed by the presiding hearing officer to provide adequate facts and law necessary for the board to deliberate and decide each case. The board's administrative hearing shall not be bound to strict rules of evidence.
E. Admissibility. Admissibility of evidence and testimony shall be determined by the presiding hearing officer as provided by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§341. Closing Arguments

A. Closing arguments may be made by respondent in proper person or by legal counsel followed by closing arguments from prosecuting legal or special counsel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§343. Board Decisions

A. The board's decision shall be based on finding(s) of fact and conclusion(s) of law. The board's decision shall be based on a preponderance of the evidence presented at a formal hearing, together with the board's determination of any appropriate sanctions, by an affirmative majority record vote of the board members participating in the decision process. Decisions shall be recorded and made part of the record.

1. Board Order. The board's order shall be rendered at the open hearing or taken under advisement and rendered within thirty days of the hearing and then served personally or domiciliary at the respondent's last known address by regular, registered, or certified mail, or by a diligent attempt thereof.
2. Finality of Board Order. The board's order becomes final eleven days after receipt of notification of the board's decision by respondent, provided an appeal is not filed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004, amended LR 33:1124 (June 2007).

§345. Complaint Dismissal

A. The board, in their discretion and based upon lack of evidence, may orally dismiss at an open hearing a pending matter or parts thereof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§347. Transcripts

A. A complete record of all formal hearing proceedings shall be transcribed, maintained, and available upon written request with sufficient costs of the preparation of the transcript for a minimum of three years from the date the pertinent order(s) is final.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§349. Contempt

A. A failure of a respondent or witness to comply with a board order, after being duly served, constitutes contempt and the board may petition a court of competent jurisdiction to rule the witness or respondent in court to show cause why he should not be held in contempt of court.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

§351. Administrative Review

A. Rehearing. An aggrieved respondent may file within ten days a rehearing motion in proper form requesting reconsideration or a rehearing by the board or by the interlocutory hearing panel.

B. Grounds. The board or an interlocutory hearing panel may reconsider the motion for rehearing at the next regularly scheduled board meeting. The grounds for such action shall be either that:

1. the board's decision was clearly contrary to the law or evidence; or
2. newly discovered evidence not available at the time of the hearing which may be sufficient to reverse the board's decision; or
3. issues not previously considered ought to be examined; or
4. it is in the public interest to reconsider the issues and the evidence.

C. Time. The board or the hearing officer shall grant or deny the petition for rehearing within thirty days after its submission.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004, amended LR 33:1124 (June 2007).

§353. Judicial Review

A. An aggrieved respondent may appeal the board's decision to a court of appropriate jurisdiction within thirty days from the board order or rehearing motion denial.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1248.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§355. Reporting

A. The board may publish in the board's newsletter the sanctions imposed by the board that are of public interest and the public's right to know.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§357. Reinstatement

A. An application for reinstatement based on revocation or suspension of a pharmacist license, pharmacy permit, certification, registration, or any other designation authorized by the board shall be filed with and heard by the reinstatement committee for consideration and recommendation to the full board. The board may then hold a formal hearing whereby the burden of proof shifts to the applicant to demonstrate and support with substantial evidence respondent's rehabilitation and that the reinstatement of the license, permit, certification, registration, or other board-authorized designation at issue would not pose a danger to the public's health, safety, or welfare.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§359. Declaratory Statements & Advisory Opinions

A. The board may issue declaratory rulings in accordance with the Administrative Procedure Act, R.S. 49:950 et seq. These may include a declaratory statement or an advisory opinion, in the form of a ruling which has the same status as board decision in adjudicated cases, in response to a request for clarification of the effect of rules and regulations or of R.S. 37:1161 et seq. Advisory opinions as a statement of the board's ruling are generally rendered in cases that relate to specific situations. Declaratory statements contain the board's ruling relative to the petition, with the principles and rationale that support the ruling. Declaratory statements are generally rendered in situations that relate to widespread situations. Neither an advisory opinion nor a declaratory statement has the binding force of law, but they represent the board's expert opinion relative to the matter in question.

B. A request for a declaratory statement or for an advisory opinion is made in the form of a petition to the board. At a minimum, the petition shall include:
   1. the name and address of the petitioner;
   2. specific reference to the statutes or rules and regulations to which the petition relates;
   3. a concise statement of the manner in which the petitioner is aggrieved by the rule, regulation, or statute, or by its potential application to the petitioner, or in which the petitioner is uncertain of its effects,
   4. a statement of whether an oral hearing is desired; and
   5. other information appropriate for the board's deliberation on the request.

C. Said petition shall be considered by the board at its next regularly scheduled meeting provided that the petition has been filed at least sixty days prior to the next scheduled board meeting.

D. The declaratory statement/advisory opinion of the board on said petition shall be in writing and mailed to petitioner at the last address furnished to the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§361. Cease and Desist Orders; Injunctive Relief

A. The board is empowered to issue an order to any person or firm engaged in any activity, conduct, or practice constituting a violation of the Louisiana Pharmacy Practice Act or the regulations promulgated thereto, directing such person or firm to forthwith cease and desist from such activity, conduct, or practice.

B. If the person or firm to whom the board directs a cease and desist order does not cease and desist the prohibited activity, conduct, or practice within the timeframe directed by said order, the board may seek, in any court of competent jurisdiction and proper venue, a writ of injunction enjoining such person or firm from engaging in the activity, conduct, or practice.

C. Upon proper showing of the board that such person or firm has engaged in the prohibited activity, conduct, or practice, the court shall issue a temporary restraining order restraining the person or firm from engaging in unlawful activity, conduct, or practices pending the hearing on a preliminary injunction, and in due course a permanent injunction shall be issued after a hearing, commanding the cessation of the unlawful activity, conduct, or practices complained of.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1124 (June 2007).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 5. Pharmacists

Subchapter A. Licensure Procedures

§501. Application

A. An application for initial pharmacist licensure, whether by examination or reciprocity, shall be submitted, with appropriate fee, to the board at least thirty days prior to any examination. An application shall expire one year after the date of receipt in the board office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

§503. Examination

A. Examination. A board-approved licensure examination shall consist of integrated pharmacy subject matters and any other disciplines the board may deem appropriate in order to demonstrate competence. An applicant shall achieve a passing score, as determined by the board, in the pharmacy examination.

B. Re-examination.

1. Following the first or second unsuccessful attempt of an examination for licensure, an applicant may be permitted to attempt that examination for licensure.
2. Following the third unsuccessful attempt of an examination for licensure, an applicant shall not be permitted to attempt that examination for licensure until one year from the date of the last examination.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004.

§505. Licensure

A. The board shall issue a license upon payment of appropriate fees when the board is satisfied the applicant is competent to practice pharmacy in the state.

1. Renewal. The board shall make the annual pharmacist license renewal application available to all currently licensed Louisiana pharmacists prior to November 1. The completed application along with the appropriate fee shall be submitted to the board by December 31 of each year. A pharmacist's renewal of licensure shall be displayed in the principal location where the pharmacist is engaged in the practice of pharmacy and in such a manner that said renewal may be seen by patrons. A renewal of licensure shall serve as proof of licensure and a pharmacist's license to practice pharmacy for that year of issuance.

a. Active. A pharmacist applicant shall pay the annual renewal fee, attain minimum continuing pharmacy education (CPE) as required, and complete and submit the annual renewal form to the board office before December 31 of each year.

b. Inactive. A pharmacist applicant may make a written request for inactive status from the board. The inactive pharmacist must complete the annual renewal form furnished by the board and submit it with the appropriate fee to the board before December 31 of each year. An inactive pharmacist shall not engage in the practice of pharmacy and is not required to obtain CPE. In order to upgrade an inactive license to active status, an inactive pharmacist shall petition the board and meet requirements of the reinstatement committee and the board. The board shall set the requirements necessary to assure competency for each individual applying for active status.

2. Expired License. A pharmacist license that has not been renewed by December 31 of each year shall expire and be null and void. The holder of an expired license may submit a written request, complete with any supporting documentation, for reinstatement to the board. The request may be referred preliminarily to the board's reinstatement committee for an informal hearing and recommendation that may be considered by the board at its next regularly scheduled meeting. The board may reinstate an expired license upon payment of applicable annual, delinquent, and lapsed license fees pursuant to R.S. 37:1184, as amended, and other conditions as the board deems appropriate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004, amended LR 33:1124 (June 2007), amended LR38:1234 (May 2012).

§507. Continuing Education Program

A. The board, recognizing that professional competency is a safeguard for the health, safety, and welfare of the public, shall require continuing pharmacy education as a prerequisite for annual licensure renewal for pharmacists.

B. Definitions.
   1. *ACPE* – Accreditation Council for Pharmacy Education.
   2. *CPE* – continuing pharmacy education, a structured postgraduate educational program for pharmacists to enhance professional competence.
   3. *CPE Unit* – a standard of measurement adopted by the ACPE for the purpose of accreditation of CPE programs. One CPE unit is equivalent to ten credit hours.

C. Requirements.
   1. A minimum of 1 1/2 ACPE or board-approved CPE units, or 15 hours, shall be required each year as a prerequisite for pharmacist licensure renewal. Of this number, no less than 3/10 ACPE or board-approved CPE units, or three hours, shall be acquired through live presentations, as designated by ACPE or the board. Alternatively, should a pharmacist choose to not acquire at least 3/10 ACPE or board-approved CPE units, or three hours, through live presentations, then he shall acquire an additional 5/10 ACPE or board-approved CPE units, or five hours, through any other acceptable method, over and above the minimum requirement, for a total of two ACPE or board-approved CPE units, or 20 hours.
   2. Pharmacists shall maintain copies of individual records of personal CPE activities at their primary practice site for two years and present them when requested by the board.
   3. When deemed appropriate and necessary by the board, some or all of the required number of hours may be mandated on specific subjects. When so deemed, the board shall notify all licensed pharmacists prior to the beginning of the year in which the CPE is required.
   4. When deemed appropriate and necessary by the board, the number of hours to be acquired through live presentations as designated by ACPE or the board may be increased. When so deemed, the board shall notify all licensed pharmacists prior to the beginning of the year in which the CPE is required.

D. Compliance.
   1. Complete compliance with CPE rules is a prerequisite for pharmacist licensure renewal.
   2. Non-compliance with the CPE requirements shall be considered a violation of R.S. 37:1241(A)(2), and shall constitute a basis for the board to refuse licensure renewal.
   3. The failure to maintain an individual record of personal CPE activities, or falsification of CPE documents, shall be considered a violation of R.S. 37:1241(A)(22).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1306 (October 1997), amended LR 29:2083 (October 2003), effective January 1, 2004, amended LR 33:1125 (June 2007).

§509. Address Change

A. A licensed pharmacist shall notify the board within ten days, with documentation, attesting to any change of mailing and/or home address. This documented notice shall include the pharmacist's full name and license number, and the old and new address.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004.

§511. Employment Change

A. A licensed pharmacist shall notify the board within ten days, with documentation, attesting to any change in employment. This documented notice shall include the pharmacist's full name and license number, the name and address of old and new employment, and the permit numbers of those pharmacies involved.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

§513. Certified Pharmacist Preceptor Program

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004, repealed LR 32:2256 (December 2006).

§514. Impairment

A. *Impairment* or *Impaired* – a condition that causes an infringement on the ability of a person to practice, or assist in the practice, of pharmacy sufficient to pose a danger to the public. Impairment may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.
B. Pharmacists shall be non-impaired.
C. Pharmacists who have knowledge another pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate is impaired shall notify the board of that fact as soon as possible.
D. Pharmacists may be subject to a medical evaluation for impairment by a board-approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, R.S. 37:1161 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1125 (June 2007).

Subchapter B. Professional Practice Procedures

§515. Prospective Drug Utilization Review

A. A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of enhancing pharmacy care and therapeutic outcomes by recognizing the following potential situations:
    1. drug over-utilization or under-utilization;
    2. therapeutic duplication;
    3. drug-disease contraindications;
    4. drug-drug interactions;
    5. inappropriate drug dosage or treatment duration;
    6. drug-allergy interactions; or
    7. clinical abuse/misuse.
B. Upon recognizing any of the above situations, the pharmacist, using professional judgment, shall take appropriate actions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

§517. Patient Counseling

A. Patient counseling means the effective communication by a pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.

B. Minimum Requirements. At a minimum, the pharmacist should be convinced that the patient or caregiver is informed of the following:
   1. name and description of the medication;
   2. dosage form, dosage, route of administration, and duration of therapy;
   3. special directions and precautions for preparation, administration, and use by the patient;
   4. common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required in the event of their occurrence;
   5. techniques for self-monitoring drug therapy;
   6. proper storage of the medication;
   7. prescription refill information, if any; and
   8. the action to be taken in the event of a missed dose.

C. The pharmacist may supplement oral information with written information, but shall not use written information alone to fulfill the counseling requirement.

D. Patient Information.
   1. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
      a. name, address, and telephone number;
      b. date of birth (or age) and gender;
      c. allergies/drug reactions, disease state(s); and
      d. current list of all medications.

E. Communication to the Patient.
   1. A pharmacist shall counsel the patient or caregiver "face-to-face" when possible or appropriate. If it is not possible or appropriate to counsel the patient or caregiver "face-to-face", then a pharmacist should counsel the patient or caregiver by using alternative methods. The pharmacist shall exercise his professional judgment in the selection of alternative methods, including but not limited to, telephonic or electronic communication with the patient or caregiver.
   2. A pharmacist shall provide patient counseling to patients discharged from hospitals and/or other institutions, where applicable. However, counseling shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer medication(s).
   3. The pharmacist shall maintain appropriate patient-oriented drug information materials for use by the patient upon request.

F. Waiver. No pharmacist or pharmacy may solicit or encourage blanket waivers for patient counseling. However, nothing in this regulation shall prohibit the patient or caregiver from declining patient counseling.

AUHTORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

§519. State of Emergency

A. When the Governor issues, or renews, a "State of Emergency" pursuant to the Emergency Assistance and Disaster Act of 1993, R.S. 29:721 et seq.,:
   1. A pharmacist may work in the affected parish(es) and may dispense a one-time emergency prescription of up to a thirty day supply of a prescribed medication if:
      a. in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and
      b. the pharmacist makes a good faith effort to reduce the information to a written prescription marked "Emergency Prescription", then file and maintain the prescription as required by law.
   2. A pharmacist not licensed in Louisiana, but currently licensed in another state, may dispense prescription medications in the affected parish or parishes during the time a state of emergency exists when:

a. the pharmacist has some type of identification to verify current unrestricted licensure in another state;
b. the pharmacist is engaged in a legitimate relief effort during the emergency period; and
c. the pharmacist and pharmacy notify the board of their presence and approximate location in the affected parish or parishes prior to the engagement of professional practice.

B. The authority provided for in this section shall cease with the termination of the state of emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004, amended LR 33:1125 (June 2007).

§521. Prescription Orders to Administer Medications

A. Purpose. The rules of this section describe the minimum requirements for the administration of medications to patients by Louisiana-licensed pharmacists.

B. A licensed pharmacist may administer medication directly to a patient upon the prescription or order of a practitioner. Such a prescription or order shall be known as an "Authority to Administer."
   1. An Authority to Administer is valid only for the pharmacist meeting the requirements herein and is not transferable.
   2. An Authority to Administer, once granted, is valid for a period of time not to exceed six months, unless revoked sooner by the practitioner granting the order.

C. A properly executed Authority to Administer shall:
   1. identify the licensed practitioner's name, office address, and telephone number;
   2. bear the patient's name, address, gender, and date of birth;
   3. identify the medication, dose, and route of administration;
   4. identify the pharmacist authorized to administer the medication; and
   5. bear the date of the original order and the date of any authorized subsequent dose administrations.

D. Requirements. Unless otherwise specifically authorized by the board, a pharmacist shall meet the following minimum standards to qualify for an Authority to Administer:
   1. obtain and maintain a license to practice pharmacy from the board;
   2. successfully complete a board-approved course of study from a board-approved provider that:
      a. requires documentation by the pharmacist of current certification in the American Heart Association's Basic Cardiac Life Support for Healthcare Providers, its successor, or board-approved equivalent;
      b. is an evidence-based didactic course that meets current Centers for Disease Control and Prevention (CDC) training guidelines, or other guidelines as designated by the board, and provides a minimum of twenty hours of instruction and experiential training in the following content areas:
         i. standards for medication administration practices;
         ii. basic immunology;
         iii. recommended medication administration schedules;
         iv. vaccine storage and management;
         v. informed consent;
         vi. physiology and techniques for medication administration;
         vii. pre- and post-administration assessment and counseling;
         viii. medication administration record management; and
         ix. management of adverse events, including identification and appropriate response, as well as documentation and reporting; and
      c. provides documentation of the successful completion of the course to the participant.
         i. The pharmacist shall display the certificate of completion in the primary practice site.
         ii. The pharmacist shall submit a copy of said certificate to the board office for placement in the pharmacist's permanent file.

E. The pharmacist shall maintain continuing competency to accept an Authority to Administer, as evidenced by:

1. a current certification by the American Heart Association's Basic Cardiac Life Support for Healthcare Providers, its successor, or board-approved equivalent; and
2. successful completion of at least one hour of continuing education per year related to this area of practice.

F. Vaccines. The pharmacist shall maintain and furnish the following information to the practitioner within twenty-four hours of the administration:
1. name and address of the patient;
2. age of the patient, if under fourteen years of age;
3. name of the patient's primary care physician as provided by the patient or patient's agent;
4. name, manufacturer, and lot number of the vaccine administered;
5. amount administered;
6. date of vaccine administration;
7. site of vaccine administration;
8. route of administration; and
9. name, address, and telephone number of the pharmacist administering the vaccine.

G. A pharmacist certified to administer medications may train a pharmacy intern to administer medication, provided the pharmacy intern meets the same educational requirements and minimum standards identified in Subsections D.2 and E of this Section. The intern shall be under the direct and immediate supervision of the certified pharmacist at all times during such training activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004, amended LR 34:1409 (July 2008).

§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 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 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 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 and 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 are 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 are 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 an 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, and 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

iv. 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 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.

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).

§525. Cognitive Services

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

Cognitive Services – those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information. Such services may include, but are not necessarily limited to, the following:

a. Drug regimen review, drug use evaluation and drug information;
b. Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration and disposal of drugs within the facility;
c. Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration and disposing of drugs and devices;
d. Assuring the compliance with all applicable laws, rules and regulations;
e. Provision of educational and drug information sources for the education and training of the facility health care professionals;
f. Accepting responsibility for the implementation and performance of review of quality-related or sentinel events.

B. Practice

1. A pharmacist who provides cognitive services to Louisiana residents shall be licensed by the board.
2. Cognitive services provided from outside a permitted pharmacy may not include the physical dispensing of medications to patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1234 (May 2012).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 7. Pharmacy Interns

§701. Definition

A. A *pharmacy intern* is an individual who is not yet licensed as a pharmacist in any jurisdiction, and is:

1. engaged in the practice of pharmacy while under the direct and immediate supervision of a pharmacist for the purpose of obtaining practical experience for licensure as a pharmacist, and is satisfactorily progressing in a board-approved college of pharmacy; or
2. a graduate of a board-approved college of pharmacy awaiting examination for licensure; or
3. a graduate who has established educational equivalency through a program approved by the board; or
4. an individual participating in a residency or fellowship.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1306 (October 1997), amended LR 26:2284 (October 2000), amended LR 29:2086 (October 2003), effective January 1, 2004.

§703. Registration

A. All pharmacy interns shall meet the following requirements for registration:

1. All pharmacy interns shall register with the board. The failure to register may result in disciplinary action by the board.
    a. The applicant shall submit to the board office a properly completed application no later than the end of the first semester of the first academic year at a board-approved college of pharmacy.
    b. The board may issue an Intern Registration to the applicant, upon receipt of a properly completed application, appropriate fee, and any other documentation required by the board office.
    c. The Intern Registration shall expire one year after the certification of graduation from a board-approved college of pharmacy.
    d. The Intern Registration shall be conspicuously displayed at the preceptor site.
    e. The board shall reserve the right to recall or refuse to issue any Intern Registration for cause.
2. A pharmacy intern shall wear appropriate attire and be properly identified with his name and intern status while on duty at the preceptor site.
3. A pharmacy intern shall notify the board in writing within ten days of a change of address. This notice shall include the pharmacy intern's name, registration number, and old and new addresses.
4. A pharmacy intern shall notify the board in writing within ten days of a change in location(s) of employment. This notice shall include the pharmacy intern's name and registration number, the name and address of old and new employment, and the permit numbers of those pharmacies involved.
5. The pharmacy intern shall be non-impaired.
    a. The pharmacy intern is subject to confidential random drug screen testing and/or evaluations.
    b. A positive drug screen may be self evident as proof of improper drug use. For the purposes of this chapter, a missed screen, a screen submitted beyond the mandated period, and/or any screen submitted indicating the sample provided is diluted, substituted, or in any way adulterated is considered to be a positive drug screen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 26:2285 (October 2000), amended LR 29:2086 (October 2003), effective January 1, 2004.

§705. Practical Experience

A. All applicants for licensure by examination shall earn practical experience in the practice of pharmacy concurrent with attending or after graduation from a board-approved college of pharmacy.

B. The practical experience shall be predominantly related to the provision of pharmacy primary care and the dispensing of drugs and medical supplies, the compounding of prescriptions, and the keeping of records and making of reports as required under federal and state law.

1. The practical experience earned shall have been under the supervision of a pharmacist.
2. A pharmacy intern shall not practice in a permitted pharmacy site that is on probation with the board. A pharmacy intern shall not practice under the supervision of a pharmacist whose license is on probation with the board.

C. Practical Experience Hours. To qualify for pharmacist licensure, an intern shall supply evidence of the acquisition of at least 1,500 hours of practical experience.

1. The board shall award 1,000 hours credit to an intern for his successful completion of a professional experience curriculum at a board-approved college of pharmacy. The dean of the board-approved college of pharmacy shall certify the completion of this requirement in the manner prescribed by the board office.
2. The intern shall earn at least 500 hours of practical experience in a permitted pharmacy site under the supervision of a pharmacist with no less than two years of experience as a licensed pharmacist. Further, neither the pharmacist's license nor the pharmacy's permit may be on probation with the board at the time the practical experience is earned.
3. Practical experience hours that are submitted to the board for credit consideration shall be listed on an affidavit form supplied by the board office, and signed by the pharmacist and pharmacy intern.
    a. A pharmacy intern may receive credit for a maximum of 50 hours per week.
    b. A separate affidavit shall be required from each permitted pharmacy site.
    c. No credit shall be awarded for hours earned within the professional experience curriculum of a board-approved college of pharmacy, nor for hours earned outside the professional experience curriculum but at the same time and location as hours earned for that professional experience curriculum.
4. Certification of Hours To and From Another Jurisdiction.
    a. Interns enrolled in a board-approved college of pharmacy in Louisiana who earn hours of practical experience in another jurisdiction, as well as interns enrolled in a board-approved college of pharmacy in another jurisdiction who earn hours of practical experience in another jurisdiction, may transfer those hours to Louisiana under the following conditions:
        i. The hours of practical experience shall be listed on an affidavit form supplied by the Louisiana Board of Pharmacy, signed by the preceptor pharmacist and the intern, and submitted to the Louisiana Board of Pharmacy for consideration of credit; and
        ii. The board of pharmacy in the jurisdiction where the hours were earned shall certify those hours to the Louisiana Board of Pharmacy.
        iii. The Louisiana Board of Pharmacy may grant credit for all hours that comply with the Louisiana Board of Pharmacy's requirements as delineated in this section.
    b. Upon written request by the pharmacy intern, the Louisiana Board of Pharmacy may certify practical experience hours earned in Louisiana to a board of pharmacy in another jurisdiction.
5. Credited hours of practical experience shall expire on the expiration date of the Intern Registration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 26:2285 (October 2000), amended LR 29:2086 (October 2003), effective January 1, 2004, LR 32:636 (April 2006), amended LR 33:1130 (June 2007), amended LR 34:1409 (July 2008).

§707. Impairment

A. *Impairment* or *Impaired* – a condition that causes an infringement on the ability of a person to practice, or assist in the practice, of pharmacy sufficient to pose a danger to the public. Impairment may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.

B. Pharmacy interns shall be non-impaired.

C. Pharmacy interns who have knowledge a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate is impaired shall notify the board of that fact as soon as possible.

D. Pharmacy interns may be subject to a medical evaluation for impairment by a board approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, R.S. 37:1161 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1130 (June 2007).

§709. Scope of Practice

A. Pharmacy interns may perform any duty of a pharmacist provided he is under the supervision of a pharmacist.

B. The ratio of pharmacy interns to pharmacists shall be 1:1. However, the ratio of pharmacy interns on rotation with a board-approved college of pharmacy to pharmacists shall be no more than 3:1.

C. A pharmacy intern may not:

1. present or identify himself as a pharmacist;
2. sign or initial any document which is required to be signed or initialed by a pharmacist unless a preceptor cosigns the document;
3. independently supervise pharmacy technicians; or
4. administer immunizations unless properly credentialed as required by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 36:755 (April 2010).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 9. Pharmacy Technicians

§901. Definitions

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

ACPE – Accreditation Council for Pharmacy Education.

Pharmacist Preceptor – an individual who is currently licensed as a pharmacist by the board, meets certain qualifications as established by the board, and is responsible for the instructional training of pharmacy technician candidates.

CPE – continuing pharmaceutical education, as part of a postgraduate educational program to enhance professional competence.

CPE unit – a standard of measurement adopted by the ACPE for the purpose of accreditation of CPE programs. One CPE unit is equivalent to 10 credit hours.

Pharmacy Technician – an individual, certified by the board, who assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist.

Pharmacy Technician Candidate – an individual not yet certified as a pharmacy technician by the board who is:

a. an individual who possesses a valid registration, is satisfactorily progressing in a board-approved structured program, and is working under the supervision of a pharmacist preceptor for the purpose of obtaining practical experience for certification as a pharmacy technician by the board; or

b. an individual who possesses a valid registration, has successfully completed a board-approved structured program, and is awaiting examination.

Structured Program – systematic instruction in pharmacy related functions in a board-approved pharmacy technician training program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005.

§903. Pharmacy Technician Candidates

A. Registration

1. Qualifications

a. All pharmacy technician candidates shall register with the board; failure to do so may result in disciplinary action by the board.

b. The candidate shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.

c. The candidate shall be of good moral character and non-impaired.

d. The candidate shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential.

e. Exceptions:

i. A pharmacist or pharmacist intern whose board credential has been denied, suspended, revoked, or restricted for disciplinary reasons by any board of pharmacy shall not be a pharmacy technician candidate or pharmacy technician.

ii. A pharmacist or pharmacist intern whose board credential is lapsed shall not be a pharmacy technician candidate or pharmacy technician until such lapsed credential is recalled through non-disciplinary board action.

2. Issuance and Maintenance

a. Upon receipt of a properly completed application, appropriate fee, proof of enrollment in a board-approved structured program, and any other documentation

required by the board, the board may issue a Pharmacy Technician Candidate Registration to the applicant.

b. The board reserves the right to refuse to issue, recall, or discipline a registration for cause.

c. The registration shall expire 18 months after the date of issuance, and it shall not be renewable.

d. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the candidate's name, registration number, and old and new addresses.

e. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change in either training program site or location(s) of employment. The written notice shall include the candidate's name, registration number, and name, address, and permit numbers for old and new training program sites or employers.

B. Structured Program

1. All structured programs shall meet competency standards as established by the board.
2. The curriculum of the structured program shall be composed of the elements contained in the *Pharmacy Technician Training Program Minimum Competencies*, as approved by the board.
3. The structured program shall notify the board when a pharmacy technician candidate is no longer satisfactorily progressing in the program.
4. The structured program shall provide an appropriate credential to the candidate who has successfully completed the program.

C. Practical Experience

1. The candidate shall possess a registration prior to earning any practical experience in a pharmacy.
2. The candidate's registration shall be conspicuously displayed in the prescription department.
3. The candidate shall wear appropriate attire and be properly identified as to name and candidate status while on duty in the prescription department.
4. A candidate shall not work in a permitted site that is on probation with the board, or with a pharmacist who is on probation with the board.
5. The candidate's registration shall evidence his authority to earn a minimum of 600 hours of practical experience in a pharmacy, under the supervision of a pharmacist preceptor, in satisfaction of the requirements for pharmacy technician certification. Of the required minimum 600 hours, not less than 200 hours shall be earned during and as part of a structured program.
6. A candidate may receive board credit for a maximum of 50 hours per week.
7. Hours of practical experience earned by a candidate shall expire one year after the expiration date of the registration.

D. Examination

1. A board-approved technician examination shall consist of integrated pharmacy subject matter and any other disciplines the board may deem appropriate in order to permit the candidate to demonstrate his competency. The candidate shall achieve a passing score, as determined by the board.
2. Re-examination

a. Following the first or second unsuccessful attempt of an examination, the candidate may be permitted to retake that examination.

b. Following the third unsuccessful attempt of an examination, the candidate shall wait one year after the date of the last examination to retake that examination. If the candidate fails to wait the prescribed one year period, the board may delay any future certification until that one year period has elapsed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, repromulgated LR 19:1025 (August 1993), amended LR 23:1307 (October 1997), LR 30:2485 (November 2004), effective January 1, 2005.

§905. Pharmacy Technician Certificate

A. Qualifications
   1. An applicant for a pharmacy technician certificate shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.
   2. An applicant shall be of good moral character and non-impaired.
   3. An applicant shall demonstrate the following educational competencies:
      a. shall be a graduate from a high school approved by a state department of education, or shall possess an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential; and
      b. shall have successfully completed a board-approved structured program for pharmacy technician education and training, as evidenced by a valid and legible copy of the appropriate credential from that program.
   4. An applicant shall demonstrate evidence of at least 600 hours of practical experience under the supervision of a pharmacist preceptor, using a form supplied by the board.
   5. An applicant shall demonstrate successful completion of a board-approved technician examination, as evidenced by a valid and legible copy of the appropriate credential.

B. Issuance and Maintenance
   1. Upon receipt of a properly completed and notarized application, properly executed preceptor affidavit(s), copies of valid and legible credentials, and the appropriate fee, and following verification that all requirements have been satisfied, the board may issue a pharmacy technician certificate to the applicant for the current renewal period.
   2. The board reserves the right to refuse to issue, recall, or discipline a certificate for cause.
   3. The annual renewal shall expire and become null and void on June 30 of each year.
      a. The board shall make available, no later than May 1 of each year, an application for renewal to all pharmacy technicians to the address of record.
      b. The completed application, along with the appropriate fee, shall be submitted to the board by June 30 of each year.
      c. A pharmacy technician shall not assist in the practice of pharmacy in Louisiana with an expired renewal.
      d. An application for an expired pharmacy technician renewal, along with the appropriate fee, shall be submitted to the board's Reinstatement Committee for consideration.
   4. A pharmacy technician shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the technician's name, certificate number, and old and new addresses.
   5. A pharmacy technician shall notify the board, in writing, no later than 10 days following a change in location(s) of employment. The written notice shall include the technician's name, certificate number, and name, address, and permit numbers for old and new employers.
   6. Upon written request of any certified pharmacy technician in active military service of the United States or any of its allies, the board may waive the requirement for the annual renewal of the certificate, including fees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, repromulgated LR 19:1025 (August 1993), LR 30:2486 (November 2004), effective January 1, 2005, amended LR 38:1235 (May 2012).

§907. Scope of Practice

A. Pharmacy technician candidates and pharmacy technicians may assist the pharmacist by performing those duties and functions assigned by the pharmacist while under his direct and immediate supervision.
   1. The ratio of candidates to pharmacists on duty shall not exceed one to one at any given time.
   2. The ratio of technicians to pharmacists on duty shall not exceed two to one at any given time. However, the ratio of technicians to pharmacists on duty may be increased to three to one if no technician candidates are on duty at the same time.

B. Pharmacy technician candidates shall not:
   1. receive verbal initial prescription orders;
   2. give or receive verbal transfers of prescription orders;

3. interpret prescription orders (however, a technician candidate may translate prescription orders);
4. compound high-risk sterile preparations, as defined by the United States Pharmacopeia (USP), or its successor.
5. counsel patients.

C. Pharmacy technicians shall not:
1. release a verbal prescription order for processing until it is reduced to written form and initialed by the receiving technician and supervising pharmacist;
2. interpret prescription orders (however, a technician may translate prescription orders);
3. compound high-risk sterile preparations, as defined by the United States Pharmacopeia (USP), or its successor;
4. counsel patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005, amended LR 32:1049 (June 2006).

§909. Continuing Education

A. A minimum of one ACPE or board-approved CPE unit, or 10 credit hours, shall be required each year as a prerequisite for annual renewal of a pharmacy technician certificate. Such CPE units shall be credited in the 12-month period prior to the expiration date of the certificate.

B. Certified pharmacy technicians shall maintain copies of their individual records of personal CPE activities at their primary practice site for at least 2 years, and shall present them when requested by the board.

C. If judged appropriate by the board, some or all of the required number of hours may be mandated on specific subjects. When so deemed, the board shall notify all certified pharmacy technicians prior to the beginning of the renewal year in which the CPE is required.

D. Complete compliance with CPE rules is a prerequisite for renewal of a pharmacy technician certificate.
1. Non-compliance with the CPE requirements shall be considered a violation of R.S. 37:1241(A)(2) and shall constitute a basis for the board to refuse annual renewal.
2. The failure to maintain an individual record of personal CPE activities, or falsifying CPE documents, shall be considered a violation of R.S. 37:1241(A)(22).
3. The inability to comply with CPE requirements shall be substantiated by a written explanation, supported with extraordinary circumstances, and submitted to the board for consideration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 17:779 (August 1991), repromulgated LR 19:1025 (August 1993), amended LR 23:1308 (October 1997), LR 30:2487 (November 2004), effective January 1, 2005.

§911. Impairment

A. Pharmacy technician candidates and pharmacy technicians shall be non-impaired.

B. Pharmacy technician candidates and pharmacy technicians who have knowledge that a pharmacist, pharmacist intern, pharmacy technician candidate, or pharmacy technician is impaired shall notify the board of that fact.

C. Pharmacy technician candidates and pharmacy technicians shall be subject to a medical evaluation for impairment by a board-approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, R.S. 37:1161 *et seq.*

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 17:779 (August 1991), repromulgated LR 19:1025 (August 1993), amended 23:1308 (October 1997), LR 30:2487 (November 2004), effective January 1, 2005.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter A. General Requirements

§1101. Pharmacy

A. Qualification. Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

B. Appearance. The applicants, including the pharmacist-in-charge, may be required to personally appear before the board prior to a board decision on the permit application.

C. Pharmacy Permit.

1. The initial pharmacy permit application shall be completed and signed by the pharmacist-in-charge and the owner of the pharmacy and submitted to the board for approval. An application for a pharmacy permit shall expire one year after the date of receipt in the board office.
2. Renewal. A pharmacy permit that has not been renewed by December 31 of each year shall expire and be null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1103. Prescription Department Requirements

A. A prescription department of a pharmacy shall provide sufficient floor space allocated to ensure that drugs are compounded and dispensed in a well lighted, ventilated, climate controlled, and safely enclosed structure.

B. Restricted. A prescription department is a restricted area.

C. Square Footage. A prescription department that is new or remodeled on or after January 1, 2004 shall be not less than three hundred (300) total square feet, and shall be inaccessible to the public.

D. Prescription Counter. A prescription counter on which to compound or dispense medications shall have a working surface of not less than a minimum of twenty-four (24) total square feet. The minimum unobstructed free working surface shall be kept clear at all times for the compounding or dispensing of prescriptions.

E. Prescription Aisle Space. The aisle space behind the prescription counter shall be not less than thirty (30) inches in width.

F. Prescription Department Plumbing. A sink equipped with hot and cold running water shall be located within the prescription department. A sink located in a pharmacy restroom shall not be sufficient to satisfy this requirement.

G. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy department and shall be a complete, accurate, and readily retrievable prescription record keeping and storage system.

H. Drug Inventory.

1. Storage. The pharmacy shall provide sufficient space on-site for proper storage of labels, prescription containers, and an adequate prescription inventory in order to compound and dispense prescription orders. Drugs that require special storage shall be properly stored.
2. Missing or Damaged Inventory. When significant drug inventory is missing or damaged for any reason, the pharmacy owner or pharmacist-in-charge shall file with the board a signed statement of the circumstances of such occurrence and evidence that the appropriate law enforcement authorities were notified as required by law.

3. Equipment. The pharmacy shall provide sufficient fixtures, equipment, and utensils to ensure that drugs are properly compounded and dispensed.

I. Pharmacy Security. The prescription department or the premises housing the prescription department shall be adequately secured by the installation of partitions and secured entrances, which shall be locked by a pharmacist and made inaccessible when the prescription department is closed. The prescription department or any premises housing a prescription department shall be adequately secured by an alarm system.

J. Emergency Access. An additional key to the prescription department may be maintained in a secure location outside the prescription department for use during an emergency. A log shall be maintained with the key, indicating the name of each non-pharmacist using this key, the date and time of entry, and the nature of the emergency.

K. References. A printed copy of the *Louisiana Board of Pharmacy Laws and Regulations* shall be maintained and readily available within the prescription department of a pharmacy. The pharmacy shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice, including but not limited to, pharmacology, drug interactions, dosing, toxicity, and patient counseling.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, amended LR 39:315 (February 2013).

§1105. Pharmacist-in-Charge

A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.

1. The acquisition of the PIC privilege shall require:

a. Possession of an active Louisiana pharmacist license;

b. Active pharmacy practice for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and

c. The completion of the Affidavit of Responsibility and Duties described below.

2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.

C. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.

E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.

F. Records. The pharmacist-in-charge shall be responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.

G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.

H. Discontinued and Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued or outdated drugs, or containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.

I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.

1. The permit holder shall notify the board within ten days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within ten days of the departure of the prior pharmacist-in-charge.

2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within ten days of the departure of the prior pharmacist-in-charge.
3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least ten days prior to this voluntary departure, unless replaced in a shorter period of time.

J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for inclusion in the pharmacy's record in the board office.

K. A pharmacist shall not hold a pharmacist-in-charge position at more than one pharmacy permit, unless approved by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, amended LR 38:1239 (May 2012).

§1107. Pharmacy Operation

A. A pharmacist shall be on duty at all times during regular open hours of the pharmacy.

B. A pharmacy shall be open for business a minimum of 10 hours per week, with said business hours posted at the building entrance in full public view from outside the premises.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, amended LR 34:1408 (July 2008).

§1109. Pharmacist Temporary Absence

A. A pharmacist shall be considered to be temporarily absent from the prescription department when not within the confines of the prescription department but remains on-site.

B. The pharmacist may be temporarily absent from the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy personnel providing the following conditions are met:
1. at least one certified pharmacy technician or pharmacy intern remains in the prescription department;
2. the pharmacist is available for emergencies;
3. the temporary absence does not exceed thirty minutes at a time and a total of sixty minutes in a twelve hour period;
4. the pharmacist reasonably believes that the security of the prescription department will be maintained in his absence; and
5. a notice is posted that includes the following information:
   a. the fact that the pharmacist is taking a break; and
   b. the time the pharmacist will return.

C. If the pharmacist, in his professional judgment, determines it necessary, all personnel shall be removed from the pharmacy and the pharmacy shall be secured for the duration of the temporary absence, and notice shall be posted indicating the pharmacy is closed.

D. During a temporary absence, certified pharmacy technicians or pharmacy interns may continue to process prescription orders, provided that no orders processed during the pharmacist's temporary absence be removed from the prescription department prior to the final check by the pharmacist.

E. If the pharmacist is absent less than five minutes from the prescription department, this absence is not considered a "temporary absence" within the meaning of this chapter and will not require a posted notice, provided the prescription department's security is not compromised.

F. If at any time the pharmacist deems it necessary to leave the on-site facility, the pharmacy shall be closed in accordance with §1111.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 27:2237 (December 2001) effective January 1, 2002, amended LR 29:2088 (October 2003), effective January 1, 2004.

§1111. Pharmacist Absence

A. A pharmacist is considered absent from the prescription department when he is not in the prescription department and is off-site.

B. When a pharmacist is absent from the prescription department, the prescription department must be securely closed and made inaccessible. A sign shall be displayed in a conspicuous position in front of the prescription department giving notice of closure. The sign shall be at least 8½ x 11 inches with the following wording in black letters at least one inch high: PRESCRIPTION DEPARTMENT CLOSED.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 24:692 (April 1998), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1113. Mechanical Drug Dispensing Devices

A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is prohibited. This prohibition shall not apply to automated medication systems as defined and provided for in Chapter 12 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004.

§1115. Advertising

A. False, fraudulent, deceptive, or misleading advertising as prohibited by R.S. 37:1241 of the Pharmacy Practice Act and this section shall include, but is not limited to, any public misrepresentation done or made with the knowledge, whether actual or constructive, that is untrue or illegal, or is said to be done falsely when the meaning is that the party is in fault for its error. Actual or constructive knowledge as used in this context shall include intentionally, negligently, mistakenly, or accidentally representing an untrue fact.

B. No person shall carry on, conduct, or transact business under a name which contains a part thereof the words “pharmacist”, “pharmacy”, “apothecary”, “apothecary shop”, “chemist’s shop”, “drug store”, “druggist”, “drugs”, or any word or words of similar or like import, or in any manner by advertisement, circular, poster, sign, or otherwise describe or refer to a place of business by the terms of “pharmacy”, “apothecary”, “apothecary shop”, “chemist’s shop”, “drug store”, “drugs”, or any word or words of similar or like import, unless the place of business is a pharmacy validly permitted by the board.

C. Pharmacies and pharmacists are prohibited from advertising professional ability, experience, integrity, or professional qualifications, or soliciting professional practice by means of providing prescribers of prescriptions with prescription forms imprinted with any material referring to a pharmacy or pharmacist.

D. No advertising shall include any reference, direct or indirect, to any controlled dangerous substance as provided for in Schedules II, III, IV, or V of RS. 40:964. The provision of coupons or vouchers for controlled substances through authorized prescribers, which accompany legitimate prescriptions for such controlled substances issued to patients, shall not be prohibited by this section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1117. Centralized Prescription Processing

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, repealed LR 33:1131 (June 2007).

Subchapter B. Pharmacy Records

§1119. Availability and Inspection

A. Pharmacy records shall be available and readily retrievable upon request for board inspection and review.

B. All records required by the laws and regulations of the board shall be provided to the board, or its agent, within seventy-two (72) hours of request, unless a shorter period is required, as determined by the board or its agent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004.

§1121. General Record Keeping

A. Requirements. A pharmacy shall maintain complete, accurate, and readily retrievable prescription drug records. All prescription drug records shall be available for board review upon request.

B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all prescription drug transactions, consisting of:

1. acquisition records – invoice receipts of drugs acquired;
2. disposition records – prescription orders dispensed or drugs sold, and
3. inventory records – drugs in current possession.

C. Retention. All records required in this section and by Louisiana law shall be retained for a minimum of two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004.

§1123. Records

A. Acquisition Records. Prescription drug acquisition records shall be required, and shall consist of documented invoices from manufacturers, wholesalers, distributors, brokers, or other sources of supply.

B. Inventory Records. Accurate and readily retrievable records regarding prescription drug acquisition invoices, distribution, and inventories shall be maintained and available for accountability and retained at the pharmacy premises. Inventories of controlled dangerous substances shall be required, where applicable, and maintained at the pharmacy.

C. Prescription Records.

1. Dispensing Prescription Files. Dispensed prescription orders shall be required and maintained for a minimum of two years from the last transaction/fill date by the pharmacy, constituting proof of dispensing by adequate prescription files properly documented with the proper medical practitioner's authority and the following information:
    a. patient's name, address, and telephone number;
    b. prescriber's name, address, telephone number, and if applicable, the Drug Enforcement Administration (DEA) registration number and signature;
    c. drug name, dosage form, strength, and quantity prescribed, as well as quantity dispensed when in variance with the original order;
    d. number of prescription refills authorized by the prescriber;
    e. prescription number;
    f. original dispensing date; and
    g. pharmacist's name or initials.
2. Prescription Refill Records. The following information shall be readily retrievable from the electronic record keeping system:
    a. date of refill;
    b. quantity dispensed when in variance with original order; and
    c. pharmacist's name, initials, or identification code.

D. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy and shall be a complete, accurate, readily retrievable prescription record keeping and storage system. An electronic record keeping system shall meet the following requirements:

1. Retrieval. The system shall provide on-line retrieval via screen or hard-copy printout of original prescription order information for those prescription orders that are currently authorized for refilling.
2. Summary. The system shall be capable of producing a daily hard-copy summary of controlled dangerous substance transactions.
3. Refills. The system shall be capable of recording and providing the dates of prescription refills and the identity of the pharmacist refilling those prescriptions.
4. Patient Profile. The system shall be capable of producing a patient profile that shall contain the following minimum information: patient's name and address/location, name of drug, dosage form, strength, route and frequency of administration, and pharmacist's identification.
5. Original Prescription Records. The prescription hard copy shall represent the original written order or original oral prescription reduced to written form manually or electronically produced by the pharmacist, and shall meet the record keeping requirements of this chapter.
6. Maintenance. The original written prescription, or the written form of an oral prescription, shall be retained on file, in numerical order, for a minimum of two years from the date of dispensing or the date of the last refill dispensed.
7. Prescription Refill Information. Records of refills shall be entered into the electronic record keeping system.
8. Record. A report of all original or refilled prescriptions dispensed shall be maintained, and shall include the following:
    a. prescription number;
    b. date of initial dispensing of the original prescription and the date(s) of refilling;
    c. total number of prescription refills dispensed to date or retrievable refill history on a visual mode of display as an alternative to appearing on the hard-copy printout;
    d. patient's name;
    e. patient's address, if required;
    f. the authorized prescriber's name;
    g. authorized prescriber's address, if required;
    h. the name, strength, dosage form, and quantity of the drug dispensed; and
    i. the last name and initial of the dispensing pharmacist.
9. Backup Support System. The electronic record keeping system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.

E. Digital Imaging of Prescriptions
1. In lieu of filing the actual original hard-copy prescription, a pharmacy may use an electronic imaging recordkeeping system, if:
    a. the system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription
    b. any notes of clarification of and alterations to a prescription shall identify the author and shall be directly associated with the electronic image of the prescription;
    c. the prescription image and any associated notes of clarification to or alterations to a prescription are retained for a period not less than two years from the date the prescription is last dispensed;
    d. policies and procedures for the use of an electronic imaging recordkeeping system are developed, implemented, reviewed, and available for board inspection; and
    e. the prescription is not for a Schedule II controlled dangerous substance.
2. In this capacity the pharmacy may retain the hard copy prescriptions in order of date scanned in lieu of numerical order.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 36:755 (April 2010).

§1125. Security

A. The electronic record keeping system shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004.

§1127. Register

A. The pharmacy shall maintain a register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004.

§1129. Confidentiality

A. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential information. If confidential health information is not transmitted directly between a pharmacist and a practitioner, but is transmitted through a data communication device, the confidential health information may not be accessed, maintained, or altered by the operator of the data communication device. Confidential information is privileged and may be released only subject to federal privacy laws and regulations, and subject to applicable Louisiana statutes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

Subchapter C. Pharmacy Opening, Closing, Change of Ownership, and Change of Location Procedures

§1131. Pharmacy Opening Procedures

A. The board has established the following procedures as a prerequisite to the opening of any pharmacy:
   1. Application Form. The applicant shall obtain a Pharmacy Permit Application and Louisiana Controlled Dangerous Substance License Application from the board. The completed form(s) shall be signed by the pharmacist-in-charge and returned to the board office, with appropriate fees, not less than thirty days prior to the anticipated opening of the pharmacy.
   2. Inspection. After the board has reviewed and approved the application, a board compliance officer shall conduct an on-site inspection of the premises.
   3. Compliance. Upon receipt of satisfactory evidence that the applicant is in complete compliance, the board shall issue a pharmacy permit and, if requested, a Louisiana Controlled Dangerous Substance License.
   4. DEA Registration. If applicable, the applicant shall obtain the appropriate application from the DEA, and then return said form, with appropriate fees, to the DEA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

§1133. Pharmacy Closing Procedures

A. A pharmacy permit holder shall notify the public and the board prior to discontinuing a prescription department operation, or upon petitioning for bankruptcy.
   1. Public Notice. The holder of a pharmacy permit shall post a closing notice in a conspicuous place in the front of the prescription department, and at all public entrance doors to the pharmacy. The closing notice to the public shall be posted not less than ten days prior to the anticipated date of closure, and the notice shall contain the following minimum information:
      a. the anticipated date of closure of the prescription department;

b. the anticipated date of transfer or relocation of prescription files, if different than closure date;
c. the name and address of the pharmacy to which the prescription files will be transferred; and
d. a statement that if a patient objects to the transfer of their prescription files to the intended recipient pharmacy, the patient shall make alternative arrangements for the transfer of their prescription files to another pharmacy prior to the anticipated file transfer date.

2. Board Notice. The holder of a pharmacy permit shall send written notice to the board not less than ten days prior to the anticipated date of closure, and the notice shall include the following minimum information:
    a. the anticipated date of closure of the prescription department;
    b. the name and address of the permitted pharmacy operating within a reasonably close proximity of the closing pharmacy that shall be the custodian of the transferred prescription files; and
    c. any prescription drug sale or transfer, with a complete drug inventory including recipient's name and address and/or seizure action, sequestration, executory process, public auction, liquidation, creditor assignment, and bankruptcy.
3. Disposition of Inventory.
    a. Drugs Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by an executed DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (Registrants Inventory of Drugs Surrendered), or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destructions.
    b. Drugs Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the DEA Form 41, or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.
    c. All Other Prescription Drugs. These drugs shall be returned to the supplier, transferred to an authorized registrant, or destroyed.
4. Surrender of Pharmacy Permit and Louisiana Controlled Dangerous Substance License. The holder of the permit and license shall surrender same to the board upon closing, accompanied by written confirmation of the:
    a. surrender of unused DEA order forms and the DEA registration certificate to the regional DEA office with a memorandum indicating the closing date of the prescription department;
    b. location of applicable records of controlled dangerous substance and other prescription drugs, order forms, inventories, acquisitions, and purchase records, with commitment to store such records for not less than two years, and to make such records available for inspection by an agent of the board; and
    c. removal of all pharmacy signage from the property.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

§1135. Pharmacy Change of Ownership Procedures

A. The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises.
    1. A change of ownership of a pharmacy is evident under the following conditions:
        a. sale of a pharmacy;
        b. death of a sole proprietor;
        c. the addition or deletion of one or more partners in a partnership;
        d. bankruptcy sale, or

e. a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

2. The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.
3. Upon receipt of the new permit, the seller shall:
   a. notify the board of the transaction, including the identity of the new owner(s); and
   b. surrender the voided pharmacy permit and voided Louisiana Controlled Dangerous Substance License to the board.
4. Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§1137. Pharmacy Change of Location Procedures

A. The board has established the following procedures for changing the location of any pharmacy that does not involve a change of ownership or divestiture of that pharmacy:
   1. The permit holder shall notify the board in writing prior to relocating a prescription department operation.
   2. The proper notice procedures for the relocation shall include the notice requirements applicable to pharmacy closing procedures noted in this subpart. However, a permit cancellation is not required for a permit holder that is moving to a location in reasonably close proximity to the original location and planning to continue pharmacy operations without a transfer of ownership. The permit holder shall notify the board for the proper re-designation of permit address and re-issuance of that same permit.
   3. Inspection. A board compliance officer shall conduct an on-site inspection of the premises following receipt of written notice in the board office and prior to the opening of a prescription department in a new location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004.

Subchapter D. Off-Site Services

§1139. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise.
   Centralized Prescription Dispensing – the fulfillment by one permitted pharmacy of a request from another permitted pharmacy to fill or refill a prescription drug order.
   On-Site Pharmacy – a permitted pharmacy which utilizes centralized prescription dispensing services from a remote dispenser or remote processing services from a remote processor.
   Remote Processing Services – the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:
   a. receipt, interpretation, or clarification of an order;
   b. data entry and information transfer;
   c. interpretation of clinical data;
   d. performance of drug utilization review; and
   e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation of physical transfer of drugs.
   Remote Dispenser – a Louisiana permitted pharmacy which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.
   Remote Processor – a Louisiana permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007), amended LR 39:313 (February 2013).

§1141. Centralized Prescription Dispensing

A. General Requirements
   1. An on-site pharmacy may obtain centralized prescription dispensing services from a remote dispenser provided the pharmacies:
      a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
      b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
   2. All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.

B. Policies and Procedures
   1. On-site pharmacies and remote dispensers engaging in the acquisition or provision of centralized dispensing services shall maintain a policy and procedure manual for reference by all personnel; it shall be made available for inspection and copying by the board.
   2. At a minimum, the manual shall include policies for:
      a. a description of how the parties will comply with federal and state laws and regulations;
      b. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling process;
      c. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
      d. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in the dispensing of the prescription drug order; and
      e. the provision of adequate security to protect the confidentiality and integrity of patient information and to prevent its illegal use or disclosure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007).

§1143. Remote Processing of Medical Orders or Prescription Drug Orders

A. General Requirements
   1. An on-site pharmacy may obtain remote processing services from a remote processor provided the pharmacies:
      a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
      b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
   2. A contract or agreement for remote processing services shall not relieve the on-site pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services. The activities authorized by this Section are intended to supplement pharmacy services and are not intended to eliminate the need for an on-site pharmacy or pharmacist.
      a. In the event the pharmacy soliciting remote processing services is located within a hospital with more than 100 occupied beds, there shall be at least one pharmacist on duty at that hospital at all times, and any remote processing services provided to that pharmacy shall be supplemental in nature.
      b. In the event the pharmacy providing remote processing services performs such services for a hospital pharmacy, the performance of all such services shall be limited to licensed pharmacists.

B. Access to Patient Information

1. The pharmacist at the remote processor shall have secure electronic access to the on-site pharmacy's patient information system and to all other electronic systems directly involved with the preparation of prescriptions that the on-site pharmacist has access to when the on-site pharmacy is operating. The pharmacist at the remote processor shall receive training in the use of the on-site pharmacy's electronic systems.
2. If an on-site pharmacy is not able to provide remote electronic access to the remote processor, both pharmacies shall have appropriate technology to allow access to the required patient information.

C. Policies and Procedures

1. On-site pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall be available for inspection and copying by the board.
2. At a minimum, the manual shall include policies and procedures for:
    a. identification of the responsibilities of each of the pharmacies;
    b. protection of the integrity and confidentiality of patient information; and
    c. maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), amended LR 38:1240 (May 2012), amended LR 39:313 (February 2013).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 12. Automated Medication Systems

§1201. Definitions

Automated Medication System – includes, but is not limited to, a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, or delivery of medications, and which collects, controls, and maintains all transaction information. An automated medication system may be profile-driven, non-profile driven, or a combination of both.

Final Checks of Work – the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician.

Floor Stock/First Dose Cabinet – a medication storage device, which shall be used by personnel, authorized by a protocol established by the pharmacist-in-charge, to gain access to doses as needed and first doses in patient care areas. In addition, a floor stock/first dose cabinet may be used to store medications in such specialty areas including, but not limited to, emergency room, surgery suite, and endoscopy suites.

Non-Profile Driven – system does not require prior or concomitant pharmacist review of medication order/prescriptions in order to gain access to the system for medication administration. A non-profile driven system may include, but is not limited to, a night drug cabinet, emergency drug kits, or floor stock/first dose cabinet.

Off-Site Facility – the location of a building that houses a licensee of the Department of Health and Hospitals, but which does not house a board permitted pharmacy.

On-Site Facility – the location of a building that houses a board permitted pharmacy.

Profile Driven – system requires that medication orders/prescriptions be reviewed by the pharmacist for appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the system, and before access is allowed into the system for medication administration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1203. System(s) Registration

A. The entire system shall be registered with the board and facilities shall meet the following conditions:
   1. Facility shall possess a:
      a. license from the Health Standards Section of the Department of Health and Hospitals, or
      b. Controlled Dangerous Substance License from the Health Standards Section of the Department of Health and Hospitals, or
      c. permit from the board.
   2. Registration fee for a facility not permitted by the board is as identified in R.S. 37:1184.C.xii.
   3. No registration fee will be assessed a board permitted pharmacy.
   4. Registration expires annually on June 30.
   5. Initial application shall be completed and signed by the registrant of the facility and the pharmacist-in-charge of the system(s). The completed, signed application and required fee shall be submitted to the board office no later than 30 days prior to installation of the system.
   6. Annual Renewal. The board shall make available an application for renewal to each registrant on or before May 1 each year. Said application shall be completed, signed, and, with annual fee, returned to the board office to be received on or before June 1 each year.
   7. Expired Registration. A registration that is not renewed shall be null and void. A renewal application for an expired registration shall be requested by the registrant and the completed, signed application may be referred to the board's reinstatement committee for disposition in accordance with R.S. 37:1230.
   8. Reinstatement. The holder of a registration that has expired may be reinstated only upon written application to the board and upon payment of all lapsed fees and a penalty to be fixed

by the board. Other conditions of reinstatement may be required at the discretion of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended LR 38:1235 (May 2012).

§1205. Pharmacist-in-Charge Responsibilities

A. The pharmacist-in-charge shall be a Louisiana licensed pharmacist and has the following responsibilities:
   1. assuring that the system is in good working order and accurately provides the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record-keeping and security safeguards.
   2. establishment of a quality assurance program prior to implementation of a system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of a system, which is evidenced by written policies and procedures developed by the pharmacist-in-charge.
   3. provide 30 days written notice to the board of removal of the system.
   4. define access to the system in policy and procedures of the pharmacy, in compliance with state and federal regulations.
   5. assign, discontinue, or change access to the system.
   6. ensure that access to the medications complies with state and federal regulations as applicable.
   7. ensure that the system is stocked/restocked accurately and in accordance with established written pharmacy policies and procedures.
   8. maintain or have access to all records of documentation specified in this Section for two years or as otherwise required by law.
   9. notify each licensed prescriber that his medication orders/prescriptions are not restricted to the limited number of medications which are stocked within a facility's automated medication system by placing a prominent notice to that effect on the cover of or near the beginning of such patient's medical chart or medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1207. Pharmacist Review

A. System shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to administration and in accordance with established policies and procedures and good pharmacy practice. A policy and procedure protocol shall be adopted to retrospectively review medications which cannot be reviewed prior to administration, as provided in LAC 46:LIII.1209.2.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1209. Policies and Procedures

A. The development of an automated medication system policy and procedures is the responsibility of the pharmacist-in-charge, who shall submit the complete automated medication system policy and procedures to the board for approval, on request. These policies and procedures shall be reviewed by the pharmacist-in-charge, at least annually and modified if needed, and such review documented. They shall include, but are not limited to, the following:
   1. criteria for selection of medications to be stored in each system, provided that in facilities licensed by the Department of Health and Hospitals, but not by the board, the selection criteria shall not include the substitution by the pharmacist of a product that is not an equivalent drug product to the product originally prescribed by the physician or practitioner without the explicit consent of the physician or practitioner;

2. criteria for medications qualifying for use with a non-profile driven system and the locations and situations that this type of system can be used in; and
3. information on the system as outlined below:
    a. access.
        i. system entry.
        ii. access codes.
        iii. system access privileges.
        iv. changing access privileges.
        v. termination of user.
        vi. temporary access codes.
        vii. password assignment.
    b. controlled substances.
        i. chain of custody.
        ii. discrepancy resolution.
    c. data.
        i. archiving.
        ii. stored/uploading to database.
        iii. backup.
    d. definitions.
    e. downtime procedures (see malfunction).
    f. emergency procedures.
    g. information security/confidentiality.
        i. patient information.
        ii. medication information.
        iii. transaction files.
        iv. information update plan.
        v. patient update plan.
        vi. information access.
    h. inspection.
    i. installation requirements.
    j. maintenance, e.g., service and repair protocols.
    k. medication administration.
        i. medication and patient validation.
        ii. administration verification.
    l. medication security.
        i. acquisition and disposition records.
        ii. proof of delivery.
        iii. chain of custody of controlled substances (institutions).
        iv. security management and control.
        v. medication loading and storage.
        vi. medication loading records.
        vii. medication containers.
        viii. cross contamination.
        ix. lot number control.
        x. inventory.
        xi. utilization review.
        xii. research.
    m. malfunction.
        i. troubleshooting.
        ii. power failure.
    n. quality assurance/quality improvement
        i. documentation and verification of proper loading and refilling of device.
        ii. removal of drugs for administration, return, or waste.
        iii. recording, resolving, and reporting of discrepancies.
        iv. periodic audits to assure compliance with policies and procedures.
    o. reports.
        i. system maintenance.
        ii. administrative functions.

iii. inventory.
iv. error.
v. discrepancies.
vi. activity.
vii. problem.

p. medication inventory management.
q. staff education and training.
r. system set-up.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1211. Documentation

A. Documentation as to type of equipment, serial number, content, policies and procedures and location shall be maintained on-site in the pharmacy for review by the board. Such documentation shall include, but is not limited to:
   1. name, address, and permit number of the pharmacy or licensed health care facility where the system is operational;
   2. manufacturer's name and model;
   3. quality assurance policies and procedures to determine continued appropriate use and performance of the system;
   4. policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance security, quality assurance, medication inventory, staff education and training, system set-up, and malfunction procedures; and
   5. a current copy of all pharmacy policies and procedures related to the use of the system shall be maintained at all off-site facility locations where the system is being used, as well as the pharmacy of the pharmacist-in-charge.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1213. Records

A. Records and/or electronic data kept by the system shall meet the following requirements:
   1. all events involving access to the contents of the system shall be recorded electronically.
   2. these internal records shall be maintained for one year by the pharmacist-in-charge and shall be readily available to the board. Such records shall include:
      a. identity of system accessed;
      b. identification of the individual accessing the system;
      c. type of transaction;
      d. name, strength, dosage form, and quantity of the drug accessed;
      e. name of the patient, or identification numbers for whom the drug was ordered;
      f. identification of the certified pharmacy technician or pharmacist stocking or restocking the medications in the system; and
      g. such additional information as the pharmacist-in-charge may deem necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1215. Security System(s)

A. System shall have adequate security system and procedures, evidenced by written pharmacy policies and procedures, to:
   1. prevent unauthorized access or use;
   2. comply with any applicable federal and state regulations; and

3. maintain patient confidentiality.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1217. Stocking and Restocking

A. *On-Site Facility System(s).* The stocking and restocking of all medications in the on-site system shall be accomplished by Louisiana licensed pharmacists and/or Louisiana certified pharmacy technicians under the supervision of Louisiana licensed pharmacists. A pharmacist must conduct final checks of work performed by a pharmacy technician. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the automated medication systems.

B. *Off-Site Facility System(s).* The stocking and restocking of all medications in the off-site system shall be accomplished by Louisiana licensed pharmacists; however, the certified pharmacy technician may stock or restock an off-site facility system provided a pharmacist is physically present at the off-site facility and supervises and verifies the stocking and/or restocking prior to use. The pharmacy shall have a mechanism in place to identify the certified pharmacy technician stocking or restocking and the pharmacist checking the accuracy of the medications to be stocked or restocked in the system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1219. Packaging and Labeling

A. All containers of medications stored in the system shall be packaged and labeled in accordance with federal and state laws and regulations and contain an established satisfactory beyond use date based on U.S.P. standards.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1221. Proof of Use

A. For medication removed from the system for patient administration, the system shall document, at a minimum, the following:
   1. name of the patient or resident;
   2. patient's or resident's medical record number or identification number, or room and bed number;
   3. date and time medication was removed from the system;
   4. name, initials, or other unique identifier of the person removing the drug; and
   5. name, strength, and dosage form of the medication or description of the medical device removed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1223. Wasted, Discarded, or Unused Medications

A. The system shall provide a mechanism for securing and accounting for wasted, discarded, or unused medications removed from the system according to policies and procedures, and existing state and federal law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1225. Inspection

A. System records shall be available and readily retrievable for board inspection and review during regular working hours of operation. The system itself is also subject to inspection at that time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1227. Out-of-State Pharmacies

A. Out-of-state pharmacies must have applied for and been issued an out-of-state pharmacy permit by the board as identified in regulations. Out-of-state pharmacies must have the proper pharmacy permit issued by the state in which they reside in order to utilize a system in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1229. Violations; Penalties

A. The board may refuse to issue or renew, or may revoke, summarily suspend, suspend, place on probation, censure, reprimand, issue a warning against, or issue a cease and desist order against, the licenses or the registration of, or assess a fine/civil penalty or costs/administrative costs against any person pursuant to the procedures set forth in R.S. 37:1245, for any violation of the provisions of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

§1231. Revised Statutes and Louisiana Administrative Code

A. These regulations shall be read and interpreted jointly with Chapter 14 of Title 37 of the Revised Statutes and Part LIII of Title 46 of the Louisiana Administrative Code.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 13. Community Pharmacy

§1301. Definition

A. A *community pharmacy* is a pharmacy located in a non-institutional environment, and is licensed by the board to conduct professional pharmacy practice activities in the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

§1303. Permit

A. A community pharmacy permit shall be required to operate a pharmacy in this state, and to dispense prescription drugs to patients in Louisiana. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

§1305. Compliance

A. A community pharmacy shall comply with all applicable federal and state pharmacy laws and regulations, including Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 15. Hospital Pharmacy

§1501. Cross References

A. For all regulations that apply to permitted hospital pharmacies concerning pharmacy practices not specifically stated in this chapter, refer to Chapters 11 and 25.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:808 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 38:1235 (May 2012).

§1503. Definitions

A. As used in this chapter, the following terms shall have the meaning ascribed to them in this Section:
Hospital Pharmacy – a pharmacy department permitted by the board and located in a hospital licensed pursuant to R.S. 40:2100 et seq. For the purposes of this chapter, a hospital pharmacy is one example of a primary care treatment modality pharmacy.
Registered Patient – A person receiving health care services within a hospital facility.
Remote Processing Services – the processing of a medical order or prescription by one pharmacy on behalf of another pharmacy, including:
a. receiving, interpreting, or clarifying a medical order;
b. entering data and transferring medical order information;
c. interpreting clinical data;
d. performing therapeutic intervention relative to medication therapy; and
e. providing drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.
Remote Processor – a permitted hospital pharmacy in Louisiana which provides remote processing services for another permitted hospital pharmacy in Louisiana.
Unit Dose – the packaging of individual prescription doses in a suitable container that have been properly labeled as to the identity of the generic, chemical, or trade name of the drug; strength; lot number; and expiration date. All unit doses qualify as "prepackaging" as used in this chapter. However, all prepackaging is not necessarily in "unit dose" packaging.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007).

§1505. Hospital Pharmacy Permit

A. A hospital pharmacy permit shall be required to operate a pharmacy department located within a hospital for registered patients in a hospital. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007).

§1507. Pharmacist-in-Charge

A. The pharmacist-in-charge of a hospital pharmacy permit shall have had at least two years of experience as a licensed and practicing pharmacist prior to accepting the appointment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1509. Drug Distribution Control

A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital facility shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.
   1. Procedure Manual. The pharmacist-in-charge shall maintain written procedures for the safe and efficient distribution of pharmaceutical products and delivery of pharmacy care. An updated copy shall be available for board inspection upon request.
   2. Inventories. The pharmacist-in-charge shall:
      a. perform an annual inventory on all controlled dangerous substances; and
      b. maintain a perpetual inventory of Schedule I and II controlled dangerous substances.
   3. Records. The pharmacist-in-charge shall maintain adequate records regarding the use and accountability of controlled dangerous substances. Proof of use records for controlled dangerous substances shall be maintained separately and in such a manner as to be readily retrievable. These records shall specify the following minimum information:
      a. drug name, strength, and quantity;
      b. dose;
      c. full name of patient;
      d. date and time of administration; and
      e. name of person administering the drug.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1511. Prescription Drug Orders

A. The pharmacist shall review the practitioner's medical order prior to dispensing the initial dose of medication, except in cases of emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

§1512. Hospital Pharmacy Prepackaging

A. Prepackaging is the preparation of medication in a unit-of-use container by credentialed pharmacy personnel in a pharmacy prior to the receipt of a prescription or medical order for ultimate issuance by a pharmacist in Louisiana.
B. Labeling. The label on the prepackaged container shall contain the following minimum information:
   1. Drug name;
   2. Dosage form;
   3. Strength;
   4. Quantity dispensed when appropriate;
   5. Special storage requirements;
   6. A unique pharmacy prepackage lot number which shall correspond to the following:
      a. Name of manufacturer and/or distributor;
      b. Manufacturer's lot or batch number;
      c. Date of preparation; and
      d. Verifying pharmacist's initials;
   7. Expiration date, according to United States Pharmacopeia (USP) guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1235 (May 2012).

§1513. Labeling

A. All drugs dispensed or compounded by a hospital pharmacy, intended for use within the facility, shall be dispensed in appropriate containers and adequately labeled as to identify patient name and location, drug name(s) and strength, and medication dose(s). Additionally, compounded preparations and sterile preparations shall be labeled with the expiration date or beyond-use date, initials of the preparer, and the pharmacist performing the final check.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 38:1235 (May 2012).

§1515. Ambulance Service Drugs

A. Hospital pharmacies that supply prescription drugs, including any controlled dangerous substances, to any authorized ambulance service or emergency medical service shall maintain proper records to ensure control, proper utilization, inventory, and accountability.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1517. Pharmacist Absence/Drug Cabinet

A. Pharmacist Absence. In the absence of a licensed pharmacist, admittance to the pharmacy by unauthorized persons is prohibited. When the pharmacy is closed, a pharmacist shall be on emergency call.

B. Drug Cabinets. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the patients by the use of drug cabinets.

1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized hospital personnel only.
2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy ensuring access to authorized personnel only.
3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of the drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances stored in the drug cabinet.
4. Labeling. Medications stored in a drug cabinet shall be properly labeled.
5. Quantities. Prepackaged drugs shall be available in amounts sufficient for immediate therapeutic or emergency requirements.
6. Accessibility. Written medical practitioner's orders and proof of use, if applicable, shall be provided when a drug cabinet inventory is utilized.
7. Inspection. Medications stored in a drug cabinet shall be inspected every thirty days.
8. Policy Manual. A policy and procedure manual shall be maintained to implement the drug cabinet requirements and is to be made available to the board upon request for inspection and approval.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

§1519. Drug Returns

A. In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy in accordance with good professional practice standards.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1521. Off-Site Pharmacy Services

A. Availability. Pharmacy services may be procured contractually from outside the hospital for inpatient administration.

B. Contractual agreements shall provide for:

1. emergency – the pharmacy provider shall be available for on-call for emergency pharmacy services.
2. storage – adequate drug storage facilities shall be provided to the pharmacy provider.
3. labeling – prescription drugs supplied to hospital inpatients shall be properly labeled to ensure that adequate control, supervision, and recall of medication are monitored.
4. contractual pharmacy service – off-site contractual pharmacy services rendered to the hospital shall be in accordance with federal and state laws, rules, and regulations.

C. A pharmacy providing off-site contractual pharmacy services to a hospital shall not be considered a hospital pharmacy.

D. Medications. Prescription medications independently supplied to registered patients shall comply with all appropriate board regulations and statutes and/or hospital rules, regulations, and policies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1523. Outpatient Pharmacy Dispensing

A. Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty classification(s) under these regulations. All records including the annual inventory of controlled dangerous substances for the outpatient pharmacy shall be maintained and kept separate and apart from that of the inpatient pharmacy, as the outpatient pharmacy may not acquire drugs through the hospital pharmacy permit under the provisions of the Robinson-Patman Act, 15 U.S.C. §13(c).

B. Nothing in this section shall prohibit the dispensing of certain prescriptions from the hospital pharmacy, as allowed under the Robinson-Patman Act, 15 U.S.C. §13, including:

1. dispensing to the hospital inpatient for use in his treatment at the hospital;
2. dispensing to the patient admitted to the hospital's emergency facility for use in the patient's treatment at that location;
3. dispensing to the hospital outpatient for personal use on the hospital premises;
4. dispensing in the context of a genuine take-home prescription, intended for a limited and reasonable time as a continuation of, or supplement to, the treatment that was administered at the hospital to the recipient while an inpatient, an outpatient, or an emergency facility patient if the patient needs that treatment; or
5. dispensing to the hospital's physicians, employees, or its students for their personal use or for the personal use of their dependents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

§1525. Remote Processing of Medical Orders

Repealed.

*[**Editor's Note:** Content transferred to §1143 in Chapter 11.]*

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), repealed LR 38:1240 (May 2012).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 17. Institutional Pharmacy

Subchapter A. General Requirements

§1701. Cross References

A. For all regulations that apply to permitted institutional pharmacies concerning pharmacy practices not specifically stated in this chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004.

§1703. Definitions

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

Institutional Facility – any organization whose primary purpose is to provide a physical environment for a patient to obtain health care services, including but not limited to a(n):

a. convalescent home;
b. nursing home;
c. extended care facility;
d. mental health facility;
e. rehabilitation center;
f. psychiatric center;
g. developmental disability center;
h. drug abuse treatment center;
i. family planning clinic;
j. penal institution;
k. hospice;
l. public health facility;
m. athletic facility.

Institutional Pharmacy – that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of an injury, illness, and disease are dispensed, compounded, and distributed and pharmacy primary care is provided, and is permitted by the board and is devoted exclusively to providing professional services to a patient in that institutional setting, other than a hospital.

Long Term Care Facility – a nursing home, retirement center, mental care, or other facility or institution that provides extended health care to a residential patient, including but not limited to health care facilities licensed by the Department of Health and Hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004.

§1705. Institutional Pharmacy Permit

A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an institutional facility, other than a hospital or penal institution, for residents or patients of that institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of these regulations.

C. Pharmacies operated within a penal institution shall be operated in accordance with Chapter 18 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004, amended LR 39:313 (February 2013).

§1707. Drug Cabinet

A. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the residents/patients by the use of drug cabinets. When the pharmacy is closed, a pharmacist shall be on emergency call.
   1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized facility personnel only.
   2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy area ensuring access by authorized personnel only.
   3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
   4. Labeling. Medications stored in a drug cabinet shall bear a label with the following minimum information:
      a. drug name;
      b. dosage form;
      c. strength;
      d. name of manufacturer and/or distributor;
      e. manufacturer's lot or batch number;
      f. pharmacist's initials; and
      g. expiration date, according to United States Pharmacopeia guidelines.
   5. Accountability. Documented medical practitioner's orders and proof of use shall be provided when any of the drug cabinet inventory is utilized.
   6. Inspection. The pharmacy shall inspect medications stored in a drug cabinet every 30 days, plus or minus five days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

Subchapter B. Emergency Drug Kits

§1709. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this section:
   Emergency Drug Kit (EDK) – for long-term care facilities or other board-approved sites, other than a hospital, means a drug kit containing designated emergency drugs which may be required to meet the immediate therapeutic needs of a resident or patient.
   Emergency Drugs – those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients or residents because of delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

§1711. Emergency Drug Kit Permit

A. A long-term care facility, institutional facility without an institutional pharmacy, or other board-approved site, other than a hospital, that desires to maintain an Emergency Drug Kit shall obtain an EDK permit from the board.

B. Permit Application and Requirements. Application for an EDK permit shall be made on a form provided by the board.

1. The provider pharmacy shall apply to the board for an EDK permit. The administrator of the applicant facility shall also sign the application for said permit. Upon compliance with the required provisions, the provider pharmacy shall be issued a permit by the board for the provider pharmacy to establish and maintain an EDK in the facility.
2. The provider pharmacy shall be a Louisiana-licensed pharmacy.
3. Only one provider pharmacy shall be assigned to and be responsible for each EDK.
4. EDK permits are institutional facility-specific and not transferable.
5. A separate permit is required for each EDK.
6. The original EDK permit shall be conspicuously displayed at the provider pharmacy. A copy of the EDK permit shall be maintained in the room where the EDK is located.

C. Pharmacist-in-Charge. The pharmacist-in-charge of the provider pharmacy shall be the pharmacist-in-charge of the EDK. The maintenance of the EDK shall at all times remain the responsibility of the pharmacist-in-charge.

D. Renewal. Each EDK permit issued by the board shall be renewed annually by the provider pharmacy, at the time designated by the board. If an EDK permit is not renewed by July 1 of each year, the existing permit shall expire and become null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

§1713. Emergency Drug Kit Requirements

A. Emergency Use. An EDK is solely intended for the immediate therapeutic emergency needs of a resident or patient.

B. Security. The EDK shall be tamper-evident and shall be maintained in a secure enclosure located within the institutional facility and shall be available for emergency use by authorized personnel only.

C. Exterior Identification and Labeling. The EDK shall be clearly labeled to indicate that it is an emergency drug kit. In addition, the attached exterior label shall have an inventory of contents and contact information of the provider pharmacy.

D. Labeling. Medications stored in an EDK shall bear a label with the following minimum information:

1. drug name;
2. dosage form;
3. strength;
4. name of manufacturer and/or distributor;
5. manufacturer's lot or batch number; and
6. expiration date, according to United States Pharmacopeia guidelines.

E. Storage. All drugs in an EDK shall be stored to ensure a proper environment for the preservation of the drugs. If federal or state laws or regulations require adequate storage outside the EDK, documentation shall be kept with the EDK properly identifying this special storage requirement and drug(s) involved.

F. Policies and Procedures. Policies and procedures shall be maintained by the provider pharmacy and the applicant facility to implement the EDK requirements.

G. Accountability. Documented medical practitioner's orders and proof of use shall be provided when an EDK inventory is utilized. Medication administered to patients from the EDK shall be documented with the following information, in accordance with the institutional facility policy manual, that shall be immediately reduced to writing and a copy delivered to the provider pharmacy:

1. name of the resident patient;
2. drug name, strength, and quantity;
3. nature of the emergency;
4. time and date of administration;
5. name of person administering the medication; and
6. name of prescriber authorizing the medication.

H. Records. Records shall be readily retrievable and comply with applicable federal and state laws and regulations.

I. Inspection.
   1. The provider pharmacy shall inspect the EDK every thirty (30) days, plus or minus five (5) days. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained and made available to the board upon request.
   2. The EDK shall be available for inspection by the board.

J. The placement of controlled dangerous substances in an EDK in non-federally registered long-term care facilities shall be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:
   1. Controlled dangerous substances shall be stored in the EDK as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;
   2. The source from which the controlled dangerous substances for EDKs are obtained shall be a pharmacy licensed by the board in possession of a valid DEA registration and Louisiana CDS license;
   3. The number of different controlled dangerous substances in a single EDK shall be limited to a maximum of eight separate drug entities with not more than eight single-use containers of each drug entity;
   4. The EDK containing controlled dangerous substances shall be closed with a tamper proof seal and kept in a located medication room, cart or closet;
   5. Access to controlled dangerous substances stored in an EDK shall be limited to the pharmacist, a practitioner, the director of nursing services, or the registered nurse or licensed practical nurse on duty;
   6. Controlled dangerous substances stored in an EDK shall be administered to a patient only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21 or their successors;
   7. A usage record shall be retained in the EDK for each separate drug included which shall be completed by the nursing staff when retrieving any controlled dangerous substance(s) from the EDK;
   8. The pharmacist at the provider pharmacy shall receive and retain all completed usage records for a minimum of two years;
   9. When the EDK is opened:
      a. The pharmacist shall be notified by the facility within 24 hours; and
      b. Shift counts shall be performed by the nursing staff on all controlled dangerous substances until the kit is resealed by the pharmacist.
   10. Shift counts of the controlled dangerous substances contained in the EDK shall not be required when the EDK is sealed;
   11. The pharmacist shall check the controlled dangerous substances in the EDK at least monthly and so document that check inside the kit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended LR 39:312 (February 2013).

Subchapter C. Drug Abuse Treatment Center Pharmacies

§1715. Purpose

A. The board may issue a pharmacy permit for a drug abuse treatment center operating in the state of Louisiana where drugs are dispensed and pharmacy primary care is provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1717. Cross References

A. For all regulations that apply to drug abuse treatment center pharmacies concerning pharmacy practices not specifically stated in this subchapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1719. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this section:

Administer or Administration – means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Authorized Personnel – means individuals who, within the scope of their authority granted by mutual agreement of the drug abuse treatment center's pharmacist-in-charge and director, are granted access to the drug abuse treatment center's pharmacy department as part of his duties.

Dispense or Dispensing – means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. "Dispense" necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent.

Drug Abuse Treatment Center – means any establishment, facility, or institution, public or private, whether operated for profit or not, which primarily offers, or purports to offer, maintain, or operate facilities for the residential or outpatient diagnosis, care, treatment, or rehabilitation of two or more non-related individuals, who are patients as defined herein, excluding, however, any hospital or mental hospital otherwise licensed by the Department of Health and Hospitals.

Patient or Client – means a person who is dependent on, or otherwise suffering physically or mentally from the use of, or abuse of, controlled dangerous substances and who requires continuing care of a drug abuse treatment center.

Perpetual Inventory – means a computer record of inventory kept continuously up to date by detailed entries of all incoming and outgoing items. This includes inventory on hand, purchases, and dispensing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

§1721. Drug Abuse Treatment Center Pharmacy Permit

A. A drug abuse treatment center pharmacy permit shall be required to operate a pharmacy department located within a drug abuse treatment facility for patients of that facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

§1723. Minimum Security Controls for Drug Abuse Treatment Centers

A. Persons enrolled in a drug abuse treatment center shall wait for their prescriptions in an area physically separated from the controlled dangerous substance (CDS) storage and dispensing area. This requirement shall be enforced by the drug abuse treatment center physician(s), pharmacist(s), and employees.

B. All CDS used in a drug abuse treatment center shall be securely locked and accessible to authorized personnel within that facility only.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

§1725. Records and Reports of Drug Abuse Treatment Centers

A. All persons licensed by the Department of Health and Hospitals to operate a drug abuse treatment center and who possess a Drug Enforcement Administration (DEA) registration to purchase, possess, and use CDS shall keep the following records:
   1. records of CDS received by approved persons, including date of receipt, name and address of distributor, type and quantity of such drugs received, and the signature of the individual receiving the CDS. A duplicate invoice or separate itemized list furnished by the distributor will be sufficient to satisfy this record requirement, provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of federal order forms for CDS listed in Schedule II must be retained; and
   2. records of CDS administered or dispensed, including date of administration or dispensing, name of patient, signature of person administering or dispensing, type and quantity of drug, and such other information as may be required by state and federal laws and regulations.

B. Records of perpetual inventories shall be kept at the permitted site as prescribed by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

Subchapter D. Drug Donations to Pharmacies in Penal Institutions

§1727. Medication Transfers

Repealed.

*[**Editor's Note:** Content transferred to §1817 in Chapter 18.]*

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:1408 (July 2008), repealed LR 39:313 (February 2013).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 18. Penal Pharmacy

§1801. Penal Pharmacy Permit

A. A penal pharmacy permit shall be required to operate a pharmacy located within a penal institution, to provide medications and pharmacy care for offenders residing in that institution or another penal institution owned and operated by that governmental organization. The pharmacy in the penal institution may also provide medications and pharmacy care to offenders assigned to that institution and residing at home or another housing location.

B. In the event a pharmacy located outside a penal institution intends to provide medications and pharmacy care on a contractual basis to offenders residing in, or assigned to, a penal institution, that pharmacy shall first obtain a penal pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012).

§1803. Permit Application Procedures

A. Application for Initial Issuance of Permit
   1. The applicant for a penal pharmacy permit shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184, to the board.
   2. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
   3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
   4. The applicant may be required to personally appear before the board or one of its committees prior to any decision on the permit application.
   5. The applicant shall be required to submit to the criminal history record check process used by the board, unless waived by the board.

B. Application for Renewal of Permit
   1. Without respect to the date of initial issuance, a penal pharmacy permit shall expire at midnight on December 31 of every year, unless surrendered, suspended, or revoked sooner in accordance with the Pharmacy Practice Act or these rules.
   2. A penal pharmacy shall not operate with an expired permit.
   3. The pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.
   4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

C. Application for Reinstatement of Expired Permit
   1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
   2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
   3. An application for the reinstatement of a permit which has been expired:
      a. Less than one year may be approved by the board's administrative personnel.
      b. More than one year but less than five years may be approved by a member of the board charged with such duties.
      c. More than five years may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.
   4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184.

D. Application for Reinstatement of Suspended or Revoked Permit
   1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
   2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
   3. The application may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012).

§1805. Maintenance of Permit

A. A penal pharmacy permit is valid only for the entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a permit be valid for any premises other than the business location for which it is issued.
B. The owner of the pharmacy shall appoint a Louisiana-licensed pharmacist as the pharmacist-in-charge of the permit. The owner of the pharmacy and the pharmacist-in-charge shall comply with the provisions of *§1105 – Pharmacist-in-Charge* of the board's rules.
C. A pharmacy contemplating permanent closure of its prescription department shall comply with the provisions of *§1133 – Pharmacy Closing Procedures* of the board's rules.
D. A pharmacy contemplating a change in ownership shall comply with the provisions of *§1135 – Pharmacy Change of Ownership Procedures* of the board's rules.
E. A pharmacy contemplating a change in location shall comply with the provisions of *§1137 – Pharmacy Change of Location Procedures* of the board's rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012).

§1807. Prescription Department Requirements

A. The prescription department of a penal pharmacy shall comply with the minimum specifications identified in *§1103 – Prescription Department Requirements* of the board's rules.
B. To ensure adequate access to medications and pharmacy care, the prescription department of a penal pharmacy shall be open for business a minimum of ten (10) hours per week, with said business hours posted at the pharmacy entrance.
C. A pharmacist shall be on duty at all times during regular operating hours of the pharmacy. When the pharmacy is closed, a pharmacist shall be available for emergency calls.
D. In the absence of a pharmacist, there shall be no access to the prescription department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012).

§1809. Drug Distribution Control

A. The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, storage, distribution, control, accountability, and patient administration and management of all drugs used in the penal institution. The administration and staff of the institution shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering and accounting for drugs.
   1. The pharmacist-in-charge shall maintain a written policy and procedure manual for the safe and efficient distribution of drug products and delivery of pharmacy care. A copy of the current version of the manual shall be available for board inspection upon request.
   2. The pharmacist-in-charge shall be responsible for making and keeping pharmacy records in compliance with the provisions of §1119 – 1129 of the board's rules.
   3. The procurement, storage, security, and recordkeeping of controlled substances shall be in compliance with the provisions of *Chapter 27 – Controlled Dangerous Substances* of the board's rules.

B. The pharmacy may utilize automated medication systems, but only in compliance with *Chapter 12 – Automated Medication Systems* of the board's rules.
C. The penal pharmacy located within a penal institution may utilize drug cabinets located outside the prescription department of that institution to provide access to a limited inventory of medications when the prescription department is closed.
   1. A drug cabinet is intended solely for the proper and safe storage of needed drugs when the pharmacy is closed, and such drugs shall be available for emergency use only by authorized institution personnel.
   2. The drug cabinet shall be a securely constructed and locked enclosure located outside the prescription department ensuring access by authorized personnel only.
   3. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances stored therein. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
   4. Medications stored in a drug cabinet shall bear a legible label with the following minimum information:
      a. Drug name, strength, and dosage form;
      b. Name of manufacturer or distributor and their lot or batch number;
      c. Expiration date, in compliance with the relevant standards from the United States Pharmacopeia (USP);
      d. For prepackaged medications, the pharmacy's lot number and initials of the pharmacist.
   5. Documented orders from the medical practitioner and proof of use records shall be provided when any medications are removed from the drug cabinet.
   6. The pharmacy shall inspect medications stored in a drug cabinet on a periodic basis, but no more than thirty days since the previous inspection.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012).

§1811. Definitions

A. As used in this Section, the following terms shall have the meaning ascribed to them in this Subsection:
   Emergency Drug Kit (EDK) – a container holding designated emergency drugs which may be required to meet the immediate therapeutic needs of an offender.
   Emergency Drugs – those drugs which may be required to meet the immediate therapeutic needs of an offender and which are not available from any other authorized source in sufficient time to prevent risk of harm to the offender because of a delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012)

§1813 Emergency Drug Kit Permit

A. A penal pharmacy located outside a penal institution intending to use one more emergency drug kits within the penal institution shall first obtain an EDK permit from the board.
B. Application for Initial Issuance of Permit
   1. The penal pharmacy shall apply to the board for the permit.
   2. The applicant shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184, to the board.
   3. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
   4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
C. Application for Renewal of Permit
   1. Without respect to the date of initial issuance, an EDK permit shall expire at midnight on June 30 of every year, unless relinquished, surrendered, suspended, or revoked sooner in accordance with the Pharmacy Practice Act or these rules.

2. An EDK shall not be maintained or used with an expired permit.
3. The penal pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.
4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

D. Application for Reinstatement of Expired Permit
1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
3. An application for the reinstatement of an EDK permit which has been expired:
   a. Less than one year may be approved by the board's administrative personnel.
   b. More than one year but less than five years may be approved by a member of the board charged with such duties.
   c. More than five years may only be approved by the full board following a hearing to determine whether the reinstatement of the permit is in the public's best interest.
4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184.

E. Maintenance of Permit
1. EDK permits are specific to a penal institution and they are not transferable.
2. In the event multiple kits are required for a penal institution, a separate permit shall be required for each EDK.
3. The original EDK permit shall be displayed in the penal pharmacy supplying the EDK, and a copy of the permit shall be maintained in the room or area where the EDK is located.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012)

§1815 Emergency Drug Kit Requirements

A. The EDK shall be tamper-evident, shall be maintained in a secure enclosure located within the penal institution, and shall be available for emergency use by authorized personnel only.

B. The EDK shall be clearly labeled to indicate it is an emergency drug kit, and further, the attached exterior label shall identify the inventory of contents as well as contact information for the penal pharmacy responsible for maintaining the kit.

C. Medications stored in an EDK shall bear a label with the following minimum information:
1. Drug name;
2. Dosage form;
3. Drug strength;
4. Name of manufacturer and/or distributor;
5. Manufacturer's lot or batch number; and
6. Expiration date, according to relevant standards from the United States Pharmacopeia (USP).

D. The EDK shall be stored in a proper environment for the preservation of the drugs contained therein, in compliance with the relevant USP standards. In the event federal or state laws or rules require storage outside the EDK for one or more drugs in the EDK, documentation shall be maintained with the EDK properly identifying this special storage requirement and the drug(s) affected.

E. The penal institution and penal pharmacy shall maintain policies and procedures to implement and maintain these requirements. These policies and procedures may be maintained in written or electronic format and shall be available for review by the board or its agents.

F. When an authorized prescriber issues an order for the administration of a drug contained within the EDK, the order and proof of use shall be delivered in written or electronic format to the penal pharmacy; further, such records shall contain the following minimum information:
1. Name of offender;
2. Drug name, strength, and quantity;
3. Nature of the emergency;
4. Time and date of administration;
5. Name of prescriber authorizing the medication; and
6. Name of person administering the medication.

G. The penal pharmacy shall inspect the EDK periodically, but in no event more than thirty days after the previous inspection. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained by the penal pharmacy and available for review by the board or its agents.
H. The EDK shall be available for inspection by the board or its agents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012)

1817. Drug Donations to Penal Pharmacies

A. A penal pharmacy may accept the donation of a prescription drug, except a controlled substance, previously dispensed to another patient provided the following procedures are satisfied:
   1. The physical transfer of the donated drug shall be accomplished by an individual authorized to do so by the penal pharmacy.
   2. An inventory list of the drugs being donated shall accompany the drugs received in the penal pharmacy; the list shall contain, at a minimum, the name and strength of the drug, the quantity received, and expiration date. The penal pharmacy receiving the donated drugs shall maintain this list as an acquisition record.
   3. The penal pharmacy shall not knowingly accept the donation of any expired drugs. In the event expired drugs are received by a penal pharmacy, the pharmacist-in-charge shall destroy them as required by law.
   4. The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to its receipt in the penal pharmacy.
   5. The drug name, strength, and expiration date shall remain on the medication package or label.
B. The pharmacist-in-charge of the penal pharmacy receiving donated drugs shall be responsible for determination of suitability of the drug product for reuse.
   1. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
   2. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
   3. No product shall be re-dispensed more than one time.
C. Once accepted by the penal pharmacy, under no circumstances may the donated drugs be transferred to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012).

§1819. Medication Use Procedures

A. The pharmacist shall review the practitioner's medical order or prescription prior to dispensing or otherwise provide access to the initial dose of the medication, except in cases of emergency.
B. All drugs dispensed by the pharmacy or held for administration to offenders at the institution shall be packaged in appropriate containers that comply with the relevant standards of the USP.
C. The compounding of drug preparations shall comply with the relevant standards of the USP, as well as the provisions of §2531 – 2537 of the board's rules.
D. All drugs dispensed by the pharmacy, intended for use within the penal institution, shall be labeled as to identify the offender's name and location as well as the drug name and strength. Further, compounded preparations shall include the expiration date or beyond-use date, initials of the preparer, and initials of the pharmacist performing the final check on the label.
E. Drugs dispensed by the penal pharmacy may be returned to that penal pharmacy for re-use, in accordance with good professional practice procedures, subject to the following limitation.
   1. Drugs returned to the penal pharmacy for re-use shall not be further distributed to another entity.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1239 (May 2012).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 19. Nuclear Pharmacy

§1901. Cross References

A. For all regulations that apply to permitted nuclear pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1903. Definitions

A. As used in this chapter, the following terms shall have the meaning ascribed to them in this Section:
Nuclear Pharmacy – a board-approved facility limited to procuring, possessing, compounding, or dispensing radiopharmaceuticals or any interventional drug used in conjunction with nuclear medicine procedures. This definition shall not apply to hospital nuclear medicine departments and nuclear medicine clinics operating under the auspices of a licensed practitioner of medicine.
Radiation – any electromagnetic or ionizing radiation including gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles.
Radioactive Material – any solid, liquid, or gas that emits radiation spontaneously.
Radiopharmaceutical – a drug that is a radioactive material and includes any drug that is intended to be made radioactive, as defined by the appropriate federal agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1905. Nuclear Pharmacy Permit Requirements

A. A nuclear pharmacy permit shall be required to operate a nuclear pharmacy department. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.
   1. A nuclear pharmacy shall have a Louisiana Radioactive Material License.
   2. Nuclear Pharmacist-in-Charge. A pharmacist-in-charge of a nuclear pharmacy operation shall be a qualified nuclear pharmacist, as defined in §1907, and shall be responsible for the entire nuclear pharmacy operation.
   3. Structural Requirements. A nuclear pharmacy shall provide adequate space separate and apart from other areas commensurate with the scope of service and with the following space requirements:
      a. Dispensing Area. The radiopharmaceutical compounding or preparation area shall be separate and apart from other facility areas and shall be not less than 300 square feet, which may include storage and decay areas. The pharmacy area shall be sufficient to provide a work environment for the safe handling, compounding, and dispensing of radiopharmaceuticals. This area shall be separate and inaccessible to non-pharmacy personnel.
      b. Delivery and Receipt Area. An area designated for the delivery and receipt of materials requiring after-hours handling by non-pharmacy personnel. This area shall be separate from the dispensing area of the pharmacy.
      c. Storage Area. A storage area sufficient to maintain the scope and content of unused and returned material for decay and disposal commensurate with the compounding and dispensing requirements of the facility.
      d. Maintenance. A nuclear pharmacy shall be well maintained, clean, orderly, lighted, and properly ventilated.

e. Plumbing. A sink equipped with hot and cold running water shall be located within the nuclear pharmacy. A sink located in a pharmacy lavatory or restroom shall not be sufficient to satisfy this requirement.

4. Equipment. There shall be adequate equipment commensurate with the scope of services required and provided by the facility.
5. Supplies. There shall be adequate supplies commensurate with the compounding and dispensing needs of the facility, as well as any other services provided for by the facility, including appropriate shielding and safety devices and any other supplies necessary for the safe and legal transport of materials compounded or dispensed from the facility. There shall be appropriate supplies for the safe handling and disposal of used and unused material by employees and staff of the facility. The appropriateness of personal protective equipment shall be reviewed on an annual basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1907. Qualified Nuclear Pharmacist

A. A qualified nuclear pharmacist shall be a currently licensed pharmacist in the state of Louisiana who is listed on a Louisiana Radioactive Material License.
B. Continuing Education. Nuclear pharmacists shall obtain at least five hours of the total required hours of Accreditation Council for Pharmacy Education (ACPE) or board-approved continuing education on those applications and procedures specific to nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

§1909. Labeling

A. Immediate Container. The immediate container that comes into direct contact with the radiopharmaceutical shall be labeled with:
    1. the standard radiation symbol;
    2. the words “Caution – Radioactive Material”;
    3. the prescription control number;
    4. the name of the radionuclide; and
    5. the amount of radioactive material contained, in the appropriate unit of measure.
B. Outer Container. In addition to any labeling requirements of the board for non-radiopharmaceuticals, the outer container of a radiopharmaceutical to be dispensed shall also be labeled with:
    1. the standard radiation symbol;
    2. the words “Caution – Radioactive Material”;
    3. the name of the radionuclide;
    4. the chemical form;
    5. the amount of material contained, in the appropriate unit of measure;
    6. the liquid volume expressed in cubic centimeters or milliliters, where applicable; and
    7. the calibration time and date for the amount of radioactivity contained.
C. The labeling requirements in this Section shall not apply to transport containers.
D. Practitioner Administered Compounds Labeling. All practitioner administered compounds, as defined in Chapter 25 of these regulations, shall be dispensed or delivered in a suitable container with a label containing the following information:
    1. pharmacist’s name or initials;
    2. pharmacy’s name, address, and telephone number;
    3. preparation name;
    4. prescription number or pharmacy-assigned identification number;
    5. lot number;
    6. beyond-use date;
    7. strength and concentration;
    8. practitioner’s name; and
    9. special storage requirements, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§1911. Quality Control & Quality Assurance

A. Quality control of radiopharmaceuticals is required on all radiopharmaceuticals compounded in a nuclear pharmacy. Appropriate quality assurance procedures shall be developed and followed for the procurement, compounding, and dispensing of all pharmaceuticals in a nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 21. Charitable Pharmacy

§2101. Cross References

A. For all regulations that apply to permitted charitable pharmacies concerning pharmacy practices not specifically stated in this chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§2103. Definitions

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

Charitable Pharmacy – the practice of pharmacy at a site where prescriptions are dispensed by a charitable organization free of charge to appropriately screened and qualified patients. For the purposes of the Louisiana Administrative Code and the Pharmacy Practice Act, a "charitable pharmacy" may at times also be referred to as a "provisional permitted pharmacy."

Qualified Patients – those patients who are without sufficient funds to obtain medications as determined by strict screening guidelines based on needs assessment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§2105. Charitable Pharmacy Permit Requirements

A. A charitable pharmacy permit shall be required to operate a pharmacy in the state to dispense free prescription drugs to qualified patients in Louisiana. This permit shall only be granted to an organization qualified as a charitable organization by the U. S. Internal Revenue Code under 26 U.S.C. §501(c)(3), or its successor.
B. Compliance. The charitable pharmacy shall be in compliance with applicable federal, state, and local laws and/or regulations pertaining to the practice of pharmacy.
C. Guidelines. Strict screening guidelines based on needs assessment shall be developed by the charitable pharmacy to determine who is eligible as a qualified patient.
D. Review. All screening guidelines, needs assessments, and revisions shall be submitted to the board upon request.
E. Patient Dispensing. Prescriptions filled in a charitable pharmacy may only be dispensed to qualified patients of that pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2099 (October 2003), effective January 1, 2004.

§2107. Prescription Drug Samples

A. A charitable pharmacy shall not sell, purchase, or trade prescription drug samples.
B. A charitable pharmacy shall only possess and dispense prescription drug samples if the following conditions are satisfied:
    1. The prescription drug samples are dispensed at no charge to qualified patients of that charitable pharmacy; and
    2. The prescription drug samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. §301 et seq, or its successor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1307 (October 1997), amended LR 29:2099 (October 2003), effective January 1, 2004.

§2109. Medication Transfers

A. In facilities licensed by the Department of Health and Hospitals where United States Pharmacopeia (USP) storage requirements can be assured, prescription drugs, except controlled dangerous substances, dispensed in unit dose or in individually sealed doses may be transferred to a permitted charitable pharmacy for relabeling and dispensing to indigent patients, free of charge, pursuant to a valid prescription order.
    1. The pharmacist-in-charge of the permitted charitable pharmacy shall be responsible for determination of suitability of the product for reuse.
        a. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
        b. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
        c. No product shall be re-dispensed more than one time.
    2. Pursuant to a voluntary agreement between the facility licensed by the Department of Health and Hospitals and a pharmacy holding a charitable pharmacy permit from the board, prescription drugs, except controlled dangerous substances, may be transferred from the facility to the pharmacy provided the following procedures are satisfied;
        a. The physical transfer shall be accomplished by an individual authorized to do so by the charitable pharmacy.
        b. The patient from whom the prescription medication was obtained shall document their consent for the donation; the consent shall be maintained on file at the facility.
        c. The patient's name, prescription number, and any other identifying marks, shall be obliterated from the packaging prior to removal from the facility.
        d. The drug name, strength, and expiration date shall remain on the medication package or label.
        e. An inventory list of the drugs shall accompany the drugs being transferred. The list shall contain, at a minimum, the medication name, strength, quantity, and expiration date.
        f. Expired drugs shall not be transferred. In the event expired drugs are received by a charitable pharmacy, the pharmacist-in-charge shall destroy them as required by law

B. Under no circumstances may these transferred medications be re-distributed to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2099 (October 2003), effective January 1, 2004.

§2111. Prohibitions

A. A charitable pharmacy shall not purchase, possess, trade, distribute, or dispense controlled dangerous substances.

B. A charitable pharmacy shall not be operated, or in any way associated, with any for-profit pharmacy permitted in this state or any other jurisdiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2099 (October 2003), effective January 1, 2004.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 23. Out-of-State Pharmacy

§2301. Purpose

A. Out-of-State Pharmacies shall comply with the provisions of this Chapter in order to be and remain permitted to operate in Louisiana as an out-of-state pharmacy.

B. This Chapter applies to any place physically located outside the state of Louisiana that provides services in the state of Louisiana where prescription drugs are dispensed and/or pharmacy care is provided to residents of the state of Louisiana. This includes, but is not limited to, pharmacies providing goods and services via U.S. mail carrier, commercial carrier, the Internet, and/or directly to Louisiana residents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992) effective January 1, 1993, amended LR 29:2099 (October 2003), effective January 1, 2004.

§2303. Out-of-State Pharmacy Requirements

A. The out-of-state pharmacy shall hold a current pharmacy permit in good standing in the state(s) in which it is located and/or practicing pharmacy.

B. Each pharmacist dispensing drugs into Louisiana shall be licensed as a pharmacist in good standing in the state(s) where he practices.

C. Every out-of-state pharmacy doing business in Louisiana by dispensing and delivering prescription drugs and devices to Louisiana residents shall designate a resident agent and a registered office in Louisiana for the service of process.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004.

§2305. Out-of-State Pharmacy Permit Requirements

A. The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.

B. The out-of-state pharmacy shall pay an annual permit fee as defined in R.S. 37:1184.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004.

§2307. Pharmacist-in-Charge

A. Designation. A pharmacist licensed by the Louisiana Board of Pharmacy shall be named in the application as the pharmacy's pharmacist-in-charge for the Louisiana permit and shall be responsible for the pharmacy permit's compliance.

B. The pharmacist-in-charge shall have an active and current license in the state in which the pharmacy is located, and further, shall not have any restrictions that prohibit the position of pharmacist-in-charge.

C. Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state

pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the development and maintenance of policies regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.

E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.

F. Records. The pharmacist-in-charge is responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.

G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.

H. Discontinued or Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued drugs, outdated drugs, or drug containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.

I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.

1. The permit holder shall notify the board within ten days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within ten days of the departure of the prior pharmacist-in-charge.
2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within ten days of the departure of the prior pharmacist-in-charge.
3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least ten days prior to this voluntary departure, unless replaced in a shorter period of time.

J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This notarized document shall be submitted to the board for inclusion in the pharmacy's record in the board office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

§2309. Applicable Laws and Regulations

A. Louisiana pharmacy laws and regulations shall be applicable to regulate the practice of pharmacy for that portion of the out-of-state pharmacy's Louisiana pharmacy practice or operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004.

§2311. Inspection

A. The facilities and records of the out-of-state pharmacy shall be subject to inspection by the board or its designated agent(s).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2313. Records

A. Records shall be maintained for not less than two years.

B. The pharmacy shall maintain records of drugs dispensed to Louisiana residents in such a manner so as to be identifiable, readily retrievable, and available upon request. Said records shall be made available for inspection by the board. The pharmacy permit holder or the pharmacist-in-charge shall produce within seventy-two (72) hours any information, documentation, and/or records requested by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2315. Counseling Services

A. The pharmacy shall maintain an incoming toll-free telephone number for use by Louisiana consumers during regular office hours. Readily available telephone counseling services shall be provided that are consistent with the reasonable standard of due care. This telephone number, plus other numbers available for use, shall be printed on each container of drugs dispensed to Louisiana residents. The toll-free telephone number shall have sufficient extensions to provide reasonable access to incoming callers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2317. Out-of-State Pharmacy Closure Procedures

A. Notice. Notice shall be afforded the board not less than ten days prior to the anticipated closure date of an out-of-state pharmacy. Said notice shall include the location of all transferred prescription files for Louisiana residents.

B. Permit. The out-of-state pharmacy permit holder shall surrender the pharmacy permit to the board upon closure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2319. Jurisdiction

A. Out-of-state pharmacies soliciting, receiving, and dispensing and delivering prescription drugs and devices, including controlled dangerous substances as defined in 21 U.S.C. 1, et seq. and 21 CFR 1 et seq., or their successors, and delivered to residents in Louisiana constitutes doing business in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2101 (October 2003), effective January 1, 2004.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

Subchapter A. Durable Medical Equipment

§2401. Definitions

A. As used in this chapter, the following terms shall have the meaning ascribed to them in this Section:
"Durable medical equipment" (DME) means technologically sophisticated medical devices that may be used in a residence, including the following:
(1) Oxygen and oxygen delivery system;
(2) Ventilators;
(3) Respiratory disease management devices;
(4) Continuous positive airway pressure (CPAP) devices;
(5) Electronic and computerized wheelchairs and seating systems;
(6) Apnea monitors;
(7) Transcutaneous electrical nerve stimulator (TENS) units;
(8) Low air loss cutaneous pressure management devices;
(9) Sequential compression devices;
(10) Feeding pumps;
(11) Home phototherapy devices;
(12) Infusion delivery devices;
(13) Distribution of medical gases to end users for human consumption;
(14) Hospital beds;
(15) Nebulizers; and
(16) Other similar equipment as determined by rule.
"Legend device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician" and/or "Rx Only", or any other designation required under federal law.
"Medical gas" means compressed oxygen and liquid oxygen intended for human consumption.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:502 (March 2013).

§2403. Durable Medical Equipment (DME) Permit

A. No person or other entity shall sell, rent or provide, or offer to sell, rent or provide, directly or indirectly, to consumers in this state any durable medical equipment, legend devices, and/or medical gas until such person has obtained a Durable Medical Equipment (DME) permit from the board.
B. A DME permit shall authorize the permit holder to procure, possess and provide legend devices to the patient or end user; however, the DME permit shall not authorize the permit holder to procure, possess, or provide any prescription medications.
C. The board shall not issue a DME permit to any person or other entity that has not registered with the Louisiana Secretary of State to conduct business within the state.
D. Licensing Procedures
1. A person or other entity desiring to obtain a DME permit shall complete the application form supplied by the board and submit it with any required attachments and the application fee to the board.
2. The applicant shall provide a complete street address reflecting the location where the applicant will hold the equipment and engage in the activity for which the permit is acquired. The board shall not issue more than one permit for the same physical space.

3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
4. A person or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2).
5. Once issued, the DME permit shall expire on August 31 of every year. No person or other entity shall engage in the provision of DME with an expired DME permit.

E. Maintenance of Permit
1. A DME permit shall be valid only for the person or other entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a DME permit be valid for any premises other than the physical location for which it is issued.
2. The DME permit holder shall inform the board in writing of any and all changes to its business location within 10 calendar days, with such notice to include both the previous and new addresses.
3. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall not serve or be used as an additional or second permit.
4. A DME provider changing ownership shall notify the board in writing 15 calendar days prior to the transfer of ownership.
   a. A change of ownership shall be evident under the following circumstances:
      i. Sale;
      ii. Death of a sole proprietor;
      iii. The addition or deletion of one or more partners in a partnership;
      iv. Bankruptcy sale; or
      v. A fifty (50) percent , or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original DME permit.
   b. The new owner shall submit a properly completed application form with all required attachments and appropriate fee to the board.

F. Renewal and Reinstatement of Permit
1. The renewal of an active DME permit shall require the submission of a completed application form supplied by the board supplemented with any required attachments and appropriate fee, prior to the expiration date of the permit.
2. The reinstatement of an expired DME permit shall require the submission of a completed application form supplied by the board supplemented with any required attachments as well as the renewal and reinstatement fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39;502 (March 2013).

§2405. Standards of Practice

A. The DME provider shall not furnish any legend device or medical gas to a patient without a prescription or medical order from a licensed practitioner with prescriptive authority.

B. General Requirements:
1. The provider shall establish a suitable facility to house the equipment, allow for equipment maintenance work space, and contain sufficient space for the storage and retrieval of all required records.
2. The provider shall maintain the facility in a clean, orderly and sanitary condition at all times.
3. The facility shall be equipped with a functioning lavatory with hot and cold running water, or in the alternative, hand washing appliances or waterless hand cleaner are available.
4. The facility shall comply with all local and state building laws and fire codes.
5. The provider shall comply with all requirements from the United States Pharmacopeia (USP), the federal Food and Drug Administration (FDA), federal Department of Transportation (DOT) and Occupational Safety and Health Administration (OSHA) relative to the storage, packaging, labeling and shipping of DME including medical gases.
6. The provider shall staff the facility with an adequate number of qualified personnel to properly render DME services in the manner prescribed by law.
7. The provider shall make services continuously available without interruption when such services are essential to the maintenance of life or when the lack of services might reasonably cause harm.
8. The provider shall implement and maintain written procedures for handling complaints, and further, shall maintain a complaint file documenting all complaints and their resolution.

C. Requirements for Providers of Medical Gas, Oxygen and Respiratory Equipment

1. The provider shall comply with the following:
   a. When transporting medical gas or oxygen in cylinder or liquid form, comply with all current DOT rules;
   b. When trans-filling medical oxygen systems, comply with FDA and all state agency requirements regarding trans-filling and repackaging;
   c. Demonstrate that medical gas and oxygen provided in cylinder or liquid form meet minimum purity standards for medical grade gas or medical grade oxygen; and
   d. Adhere to the following safety inspection requirements:
      i. Demonstrate that each piece of oxygen or respiratory equipment has been checked, is free of defects, and operates within the manufacturer's specifications;
      ii. Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
      iii. Maintain all electrical components so they do not present fire or shock hazard; and
      iv. Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
2. The provider shall comply with the following recall procedures:
   a. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
   b. Maintain a tracking system for all medical gas and oxygen delivered;
   c. Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved in the event a recall is initiated; and
   d. Maintain records for equipment that requires FDA tracking.
3. The provider shall comply with the following maintenance and cleaning requirements:
   a. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set-up;
   b. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
   c. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
   d. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment.
   e. Clean and disinfect equipment according to manufacturers' specifications;
   f. Instruct the patient or caregiver on proper cleaning techniques as specified by the manufacturer; and
   g. Ensure that all medical gas, oxygen and respiratory equipment is properly identified by a tag or label as to its current status of use, i.e., out-of-order or ready for use.
4. The provider shall implement a comprehensive preventive maintenance program which shall include the following:
   a. Procedures for problem reporting, tracking, recall, and resolution;
   b. Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
   c. Routine inspection, service, and maintenance of equipment located in the patient's home according to the manufacturer's specifications.
5. The provider shall maintain repair logs to document repair and maintenance of equipment, and such logs shall contain the following information:
   a. Type of equipment;
   b. Manufacturer;
   c. Model;
   d. Serial number;
   e. Date of repair;
   f. Specific repair made; and
   g. Name of person or company performing the repair.
6. The provider shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
7. The provider shall utilize client orientation checklists to review the following information with the patient or care giver:
   a. Instructions for use of the equipment;
   b. Safety precautions;

c. Cleaning procedures;
d. Maintenance procedures;
e. Return demonstrations on back-up oxygen systems delivered;
f. Instruction for emergency and routine contact procedures; and
g. Delivery and review of written instruction materials to ensure the patient receives adequate information to properly operate the equipment.

8. A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, an assessment of the safety of the home environment, the ability of the patient or care giver to comply with the prescription or medical order, and the ability of the patient or care giver to operate and clean the equipment as instructed.

D. Requirements for Providers of Other Durable Medical Equipment

1. Providers who sell, rent or furnish other DME or legend devices shall comply with the following:
   a. Provide proper training to personnel for the safe delivery and use of any DME or legend device; and
   b. Ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and
   c. Adhere to the following safety inspection measures:
      i. Demonstrate that each piece of DME or legend device has been checked, is free of defect and operates within the manufacturer's specifications;
      ii. Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
      iii. Maintain all electrical components so they do not present fire or shock hazard; and
      iv. Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
2. The provider shall comply with the following maintenance and cleaning requirements:
   a. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set-up;
   b. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
   c. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
   d. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment.
   e. Clean and disinfect equipment according to manufacturers' specifications; and
   f. Instruct the patient or caregiver on proper cleaning techniques as specified by the manufacturer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:503 (March 2013).

§2407. Exemptions

A. The credentialing requirements of this Subchapter shall not apply to the following persons or entities unless such persons or entities have separate business entities engaged in the business of providing DME to patients at their home:
   1. Chiropractors;
   2. Dentists;
   3. Occupational therapists;
   4. Optometrists;
   5. Physical therapists;
   6. Physicians;
   7. Podiatrists;
   8. Respiratory therapists;
   9. Speech pathologists;
   10. Veterinarians;
   11. Distributors;
   12. Home health agencies;
   13. Hospice programs;

14. Hospitals;
15. Long term care facilities;
16. Manufacturers; and
17. Pharmacies.

B. Pharmacies, long term care facilities and hospitals, although excluded from the credentialing requirements of this Subchapter, shall be subject to and comply with the standards of practice identified herein.

C. Nothing in this Subchapter shall be construed to prohibit the pre-hospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:504 (March 2013).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter A. General Requirements

§2501. Prescription Drugs and Devices

A. Prescription Drugs or Devices. A prescription drug or device is a medication or mechanism that may only be dispensed by a pharmacist on the order of a licensed practitioner and shall bear the "Rx Only" notation or any other designation of similar import required by law on the label of a commercial container.
   1. Dispensing. Prescription drugs or devices shall be dispensed only by a Louisiana-licensed pharmacist.
   2. Possession. Prescription drugs or devices shall be procured and possessed in the course of the practice of pharmacy by a permitted pharmacy.
   3. Storage. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

B. Misbranded Drugs.
   1. Misbranded drugs are:
      a. those drugs whose labeling is false or misleading in any particular manner; or
      b. those drugs whose label does not bear the name and address of the manufacturer, packer, or distributor, and does not have an accurate statement of the quantities of the active ingredients; or
      c. those drugs without an accurate monograph; or
      d. those drugs meeting the qualifications for misbranded drugs as noted in the Federal Food, Drug, and Cosmetic Act, or its successor.
   2. It is unlawful to possess or dispense misbranded drugs.

C. Adulterated Drugs.
   1. Adulterated drugs are contaminated medicinal substances having deleterious foreign or injurious materials, which fail to meet safety, quality, and/or purity standards.
   2. It is unlawful to possess or dispense adulterated drugs.

D. Expired Drugs. Expired drugs shall not be dispensed and shall be removed from the pharmacy drug inventory.

E. Recalled Drugs. Recalled drugs shall be removed from the pharmacy inventory immediately upon notice. Recalls are classified as:
   1. Class I – a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
   2. Class II – a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
   3. Class III – a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004.

§2503. Drug Returns

A. Drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

§2505. Investigational Drugs

A. All investigational drugs stored or dispensed by any pharmacy shall conform to appropriate and applicable federal and state laws and regulations pertaining to their use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

§2507. Veterinary Prescription Drugs

A. Veterinary prescription drugs are prescription medications for animal use prescribed by a licensed veterinarian pursuant to a valid veterinarian-client-patient relationship and dispensed by a licensed pharmacist to the veterinarian's client, for a legitimate medical purpose, that are unsafe for unsupervised use as defined in 21 CFR §201.105, or its successor.

B. Dispensing Requirements. Veterinary prescription drugs shall be exclusively dispensed by a duly licensed pharmacist upon the order of a licensed veterinarian, unless otherwise provided by law.

C. Labeling Requirements. Veterinary prescription drugs shall be dispensed in an appropriate container, and in addition to the labeling requirements in Chapter 11 of these regulations, shall contain the following information:

1. the commercial label inscription "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and
2. the client's name and patient's animal species.

D. Prescription Form Requirements. Prescriptions issued by a licensed veterinarian shall conform to §2511 of these regulations.

E. Storage. Veterinary prescription drugs shall be maintained in the prescription department of a pharmacy, and shall be kept separate and apart from drugs intended for human use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

§2509. Prescription Devices

A. In the interest of public health, safety, and welfare, the board may, from time to time, restrict the sale of certain devices to be dispensed only by a licensed pharmacist after a legitimate medical need has been demonstrated. A legitimate medical need includes the prevention of the transmission of communicable diseases.

B. Pharmacy Device. A pharmacy device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component or accessory, which is required under federal law to bear the label "Caution: Federal or State law requires dispensing by or on the order of a physician." and/or "Rx Only", or other designation of similar import.

1. Hypodermic Apparatus. Hypodermic means any syringe, needle, instrument, device, or implement intended or capable of being adopted for the purpose of administering drugs by subcutaneous, intramuscular, or intravenous injection.
    a. Sale. Hypodermic syringes and/or needles shall be sold or distributed only by a licensed pharmacist, physician, dentist, veterinarian, podiatrist, embalmer, drug wholesaler, surgical supplier, or other legally authorized distributor.
    b. Storage. Hypodermic syringes and/or needles shall be stored in the prescription department or in another secure area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004.

Subchapter B. Prescriptions

§2511. Prescriptions

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
Electronic Prescription – a prescription transmitted in electronic form.
Practice Affiliation – a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine.
Prescription or Prescription Drug Order – an order from a practitioner authorized by law to prescribe for a drug or device that is patient specific and is communicated by any means to a pharmacist in a permitted pharmacy, and is to be preserved on file as required by law or regulation.

B. Written Prescriptions. A written prescription shall conform to the following format:
   1. The prescription form shall not be less than four inches by five inches, and shall bear a single printed signature line.
   2. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and, if applicable, Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling the authorizing prescriber's printed name.
   3. If the authorized prescriber is a non-physician, the prescription form shall clearly indicate the authorized prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.
   4. No prescription form shall contain more than four prescription drug orders. Each prescription drug order on the form shall provide the following:
      a. check box labeled "Dispense as Written", or "DAW", or both; and
      b. the number of refills, if any.
   5. Forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.
   6. Equivalent Drug Product Interchange.
      a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.
      b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written", or "DAW", or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.
      c. For prescriptions reimbursable by Medicaid or Medicare, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary" or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

C. Oral Prescriptions.
   1. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist shall reduce the order to a written form prior to dispensing the medication.
   2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.
   3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

D. Electronic Prescriptions.
   1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if applicable, DEA registration number.
   2. If the authorized prescriber is a non-physician, the prescription form shall clearly indicate the authorized prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.

3. The pharmacist shall not select an equivalent drug product when the prescriber indicates in the check box labeled "Dispense as Written", or "DAW", or both, and electronically transmits his signature on the formatted single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.
4. Facsimile Prescription.
    a. The receiving facsimile machine of a prescription transmitted by facsimile shall be located within the pharmacy department.
    b. The prescription transmitted by facsimile shall be on a non-fading legible medium.
    c. All requirements applicable to written prescriptions in Subsection (B) shall apply to facsimile prescriptions, except Subsection (B)(6)(c).

E. Exclusion. The provisions of this section shall not apply to medical orders written for patients in facilities licensed by the Department of Health and Hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), amended LR 29:2102 (October 2003), effective January 1, 2004.

§2513. Prescription Receipt and Verification

A. Receipt of a Prescription
    1. Written. A pharmacist may receive and dispense a prescription that has been written and/or signed by the practitioner.
    2. Oral. A pharmacist may receive and dispense a prescription that has been orally communicated by the practitioner when the prescription has been reduced to hard copy.
    3. Electronic Transmission. A pharmacist may receive a prescription via electronic or other means, and then reduce to hard copy, if necessary.

B. Verification. Verification of the accuracy and authenticity of any prescription is the responsibility of the pharmacist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004.

§2515. Prescriptions Based Upon Electronic Questionnaires

A. A prescription issued solely on the results of answers to an electronic questionnaire, in the absence of a documented patient evaluation including a physical examination, is issued outside the context of a valid physician-patient relationship, and is not a valid prescription.

B. If a pharmacist has reasons to suspect that a prescription was authorized solely on the results of an electronic questionnaire and in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or in violation of the practitioner's standard of practice, include:
    1. the number of prescriptions authorized on a daily basis by the practitioner;
    2. the manner in which the prescriptions are authorized by the practitioner or received by the pharmacy, i.e., electronically;
    3. the geographical distance between the practitioner and the patient(s);
    4. knowledge by the pharmacist that the prescription was issued solely as a result of answers to an electronic questionnaire; or
    5. knowledge by the pharmacist that the pharmacy he works for directly or indirectly participates in an internet site that markets prescription drugs to the public.

C. A pharmacist who has reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or otherwise in violation of the prescriber's standard of practice, shall not fill such prescription until he has obtained proof to a reasonable certainty of the validity of such prescription.

D. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004.

§2517. Prescription Dispensing

A. Prescription dispensing means the issuance, by a licensed pharmacist, of one or more doses of medication in a suitable container, properly labeled for subsequent administration, and shall consist of the following procedures or practices:
    1. receiving and interpretation of the prescription order;
    2. assembling the drug products and an appropriate container;
    3. preparing the prescription by compounding, mixing, counting, or pouring;
    4. affixing the proper label to the final container;
    5. patient counseling as required; and
    6. transfer of possession.

B. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2519. Prescription Refills

A. Refill Authorization. Prescription refills may be dispensed only with the prescriber's authorization, as indicated on the original prescription order. In the absence of the authorized practitioner's instructions on the original prescription, the prescription shall be considered non-refillable. When all refills authorized on the original prescription have been dispensed, then authorization from the prescribing practitioner shall be obtained prior to dispensing; when such authorization has been received, a new prescription shall be prepared and it shall be issued a different prescription number.

B. Controlled Dangerous Substances.
    1. The refilling of a prescription for a drug listed in Schedule II is prohibited.
    2. A prescription for a drug listed in Schedule III, IV, or V may be refilled up to five times, if so indicated at the time issued.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

§2521. Emergency Refills

A. Using sound professional judgment, a pharmacist may refill adequate medication for a seventy-two (72) hour regimen when an emergency for medication has been adequately demonstrated and the prescribing practitioner is not available.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2523. Transfer of Prescription Information

A. Prescription Transfer Requirements
    1. Prescriptions for Controlled Dangerous Substances
        a. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements:

i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
   (a) Invalidation of the prescription.
   (b) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
   (c) Record the date of the transfer and the name of the pharmacist transferring the information.

b. The pharmacist receiving the transferred prescription information shall reduce to writing the following:
   i. Indication of the transferred nature of the prescription.
   ii. Provide all information required for a prescription for a controlled substance (full name and address of patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, and DEA registration number of the prescriber) and include:
      (a) date of issuance of original prescription;
      (b) original number of refills authorized on original prescription;
      (c) date of original dispensing;
      (d) number of valid refills remaining and date(s) and location(s) of previous refill(s);
      (e) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
      (f) name of pharmacist who transferred the prescription; and
      (g) pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.
   iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.

c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

2. Prescriptions for Drugs Other Than Controlled Dangerous Substances
   a. The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies, subject to the following requirements:
      i. Prescriptions may be transferred up to the maximum number of refills permitted by the prescriber on the original prescription.
      ii. The transferring pharmacist, intern or certified technician shall record the information itemized in Clause 1.a.i above, with the exception of DEA registration numbers.
      iii. The receiving pharmacist, intern or certified technician shall record the information itemized in Subparagraph 1.b above, with the exception of DEA registration numbers.
   b. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
   c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

B. Pharmacies Using Common Electronic Files
   1. Pharmacies using a common electronic file are not required to physically or electronically transfer prescriptions for information dispensing purposes between or among pharmacies participating in the same common prescription file; provided, however, any such common file must contain complete and adequate records of such prescriptions, and further, that a hard copy of each prescription transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription or to which the prescription is transferred.
   2. This accommodation shall comply with all state and federal laws and regulations regarding controlled dangerous substance prescription transfers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), amended LR 36:756 (April 2010).

§2525. Prescription Expiration

A. A prescription for a drug other than a controlled dangerous substance shall expire one year after the date written.
B. A prescription for a controlled dangerous substance listed in Schedule II, III, IV, or V shall expire six months after the date written.
C. Expired prescriptions shall not be refillable or renewable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2527. Prescription Labeling

A. An appropriate label shall be affixed to a proper container, and shall bear the following minimum information:
    1. pharmacy's name, address, and telephone number;
    2. prescription number;
    3. authorized prescriber's name;
    4. patient's name;
    5. date dispensed;
    6. drug name and strength;
    7. directions for use, as indicated;
    8. pharmacist's name or initials; and
    9. cautionary auxiliary labels, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

§2529. Pharmacy Prepackaging

A. *Prepackaging* is the preparation of medication in a unit-of-use container by a pharmacist in a pharmacy prior to the receipt of a prescription for ultimate prescription dispensing by a pharmacist in Louisiana.
B. Labeling. The label on the prepackaged container shall contain the following minimum information:
    1. drug name;
    2. dosage form;
    3. strength;
    4. quantity;
    5. name of manufacturer and/or distributor;
    6. manufacturer's lot or batch number;
    7. date of preparation;
    8. pharmacist's initials; and
    9. expiration date according to United States Pharmacopeia (USP) guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

Subchapter C. Compounding of Drugs

§2531. Purpose and Scope

A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug products by Louisiana-licensed pharmacists for dispensing and/or administration to patients.

B. Scope. These requirements are intended to apply to all compounded products, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or physician's office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

§2533. Definitions

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

Biological Safety Cabinet – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49, or its successor.

Class 100 Environment – an atmospheric environment that contains fewer than 100 particles, of the size 0.5 microns or less in diameter, per cubic foot of air, according to Federal Standard 209E, or its successor.

Component – any ingredient used in the compounding of a drug product.

Compounding – the preparation, mixing, assembling, packaging, or labeling of a drug or device by a pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or including the preparation of drugs or devices in anticipation of prescription orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns. Compounding does not include the compounding of drug products that are essentially copies of a commercially available product.

Cytotoxic – any pharmaceutical that has the capability of killing living cells.

Practitioner Administered Compounds – products compounded by a licensed pharmacist, upon the medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic purposes.

Sterile Compounding – compounding performed using established aseptic technique and utilizing a laminar air flow hood or other device capable of providing a sterile compounding environment. Sterile compounding shall be used when compounding parenteral medications or products, ophthalmic preparations, or any other preparation requiring sterile techniques.

Sterile Product – any dosage form devoid of viable microorganisms including, but not limited to, parenterals, injectables, and ophthalmics.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. A pharmacy shall have written procedures as necessary for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they are represented to possess.
2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment.
3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.

B. Beyond Use Date. Compounded medications shall be labeled with a beyond use date of no more than one hundred eighty (180) days, unless documentation on file supports a longer beyond use date.

C. Records and Reports. Any procedures or other records required to comply with this section shall be maintained for a minimum of two years.

D. Compounding for Prescriber's Use. Pharmacists may prepare practitioner administered compounds for a prescriber's use with the following requirements:

1. an order by the prescriber indicating the formula and quantity ordered to be compounded by the pharmacist;
2. the product is to be administered by the prescriber and not dispensed to the patient; and
3. the pharmacist shall generate a label and sequential identification number for the compounded drug.

E. Anticipated Use Products. The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.

F. Labeling of Compounded Products.

1. For patient-specific compounded products, the labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall apply.
2. All practitioner administered compounds shall be packaged in a suitable container with a label containing, at a minimum, the following information:
    a. pharmacy's name, address, and telephone number;
    b. practitioner's name;
    c. name of preparation;
    d. strength and concentration;
    e. lot number;
    f. beyond use date;
    g. special storage requirements, if applicable;
    h. assigned identification number; and
    i. pharmacist's name or initials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October 2003), effective January 1, 2004.

§2537. Requirements for Compounding of Sterile Products

A. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the practice of sterile product compounding shall notify the board prior to beginning that practice, and shall receive approval from the board.

B. Personnel.

1. The pharmacist-in-charge shall be responsible for the following:
    a. procurement, storage, compounding, labeling, dispensing, and distribution of all prescription drugs, devices, and related materials necessary in compounding and dispensing sterile products;
    b. establishment of policies and procedures for the compounding and dispensing of sterile products. The policy and procedure manual shall be current, accessible to all staff, and available for inspection by the board upon request. The policy and procedure manual shall, at a minimum, include:
        i. policies and procedures for the compounding and dispensing of sterile products;
        ii. a quality assurance program for the purpose of monitoring patient care, adverse drug reactions, personnel qualifications, training and performance, product integrity, equipment, record keeping, facilities, infection control;
        iii. guidelines regarding patient education; and
        iv. procedures for the handling and disposal of cytotoxic agents, waste, and spills.
    c. documentation of competency in aseptic techniques. The aseptic technique of each individual compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training, and at least on an annual basis thereafter.
2. Training and Education. All individuals compounding and preparing sterile products shall:

a. obtain practical and/or academic training in the compounding and dispensing of sterile products;
b. complete a minimum of one hour of American Council on Pharmaceutical Education (ACPE) or board-approved continuing education, on an annual basis, related to sterile product compounding, dispensing, and utilization;
c. use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policy and procedure manual;
d. qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to compound and dispense sterile products; and
e. maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
    i. name of the individual receiving the training/evaluation;
    ii. date of the training/evaluation;
    iii. general description of the topics covered;
    iv. signature of the individual receiving the training/evaluation; and
    v. name and signature of the individual providing the training/evaluation.

C. Physical Requirements.
1. The pharmacy shall have a designated area with entry restricted to designated personnel for preparing sterile products, and the designated area shall be:
    a. structurally isolated from other areas with restricted entry or access and shall be configured in such a manner so as to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility;
    b. used only for the preparation of these sterile products; and
    c. sufficient in size to accommodate a laminar air flow hood or other device capable of providing a sterile compounding environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
2. The pharmacy where sterile products are prepared shall have:
    a. a sink with hot and cold running water that shall be located in, or adjacent to, the area where sterile products are compounded;
    b. appropriate environmental control devices capable of maintaining at least Class 100 environment in the workplace where critical objects are exposed and critical operations are performed. These devices, e.g., laminar air flow hoods, and other zonal laminar flow hoods utilizing High Efficiency Particulate Air (HEPA) filters, shall be capable of maintaining Class 100 conditions during normal activity;
    c. appropriate refrigeration for storing supplies and sterile products requiring refrigeration subsequent to their preparation and prior to their dispensing or administration to patients. The pharmacy shall maintain documentation of refrigeration integrity, in accordance with its policies and procedures.
    d. appropriate disposal containers for used needles, syringes, and other sharps, and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes; and
    e. temperature-controlled delivery containers, when required.
3. The pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of sterile products. Within the sterile compounding area, prescription drugs, devices, and related materials shall not be stored in shipping containers constructed of corrugated cardboard or other high particulate-producing materials.
4. The pharmacy shall maintain current reference materials related to sterile products accessible to all personnel.

D. Drug Handling. Any sterile compounded product shall be shipped or delivered to a patient in appropriate temperature-controlled delivery containers as defined by USP standards and appropriately stored.

E. Cytotoxic Drugs. In addition to the minimum standards for a pharmacy established by the board, the following requirements are established for pharmacies that prepare cytotoxic drugs, to insure the protection of the personnel involved.
1. All cytotoxic drugs shall be compounded in a vertical flow, Class II Biological Safety Cabinet. Other products shall not be compounded in this cabinet.

2. Personnel compounding cytotoxic drugs shall wear protective apparel, including disposable masks, gloves, and gowns with tight cuffs.
3. Personnel compounding cytotoxic drugs shall use appropriate safety and containment techniques.
4. Prepared doses of cytotoxic drugs shall:
    a. be dispensed and labeled with proper precautions on the inner and outer containers or other device capable of providing a sterile environment; and
    b. be shipped in a manner to minimize the risk of accidental rupture of the primary container.
5. Disposal of cytotoxic waste shall comply with all applicable federal, state, and local requirements.
6. A "Chemo Spill Kit" shall be readily available in the work area, and shall consist of appropriate materials needed to clean up spills of hazardous drugs. Personnel shall be trained in its appropriate use for handling both minor and major spills of cytotoxic agents.

F. Quality Control.
1. An ongoing quality control program shall be maintained and documented that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile products meeting specifications.
    a. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to federal standards for operational efficiency at least every six months. Appropriate certification records shall be maintained.
    b. Written procedures shall be developed requiring sampling if/when microbial contamination is suspected.
    c. When bulk compounding of sterile solutions is performed using non-sterile chemicals, extensive end-product testing shall be documented prior to the release of the product from quarantine. This process shall include appropriate tests for particulate matter and testing for pyrogens.
    d. Written justification shall be maintained of the chosen "beyond use" dates for compounded products.
    e. Documentation shall be maintained of quality control audits at regular, planned intervals, including infection control and sterile technique audits.

G. Labeling.
1. All practitioner administered sterile compounds shall be packaged in a suitable container, and shall bear a label with the following minimum information:
    a. pharmacy's name, address, and telephone number;
    b. preparation name;
    c. strength and concentration;
    d. lot number;
    e. beyond use date;
    f. practitioner's name;
    g. assigned identification number;
    h. special storage requirements, if applicable; and
    i. pharmacist's name or initials.
2. The labeling for all other sterile compounds shall be in accordance with the prescription labeling requirements in §2527 of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 27. Controlled Dangerous Substances

Subchapter A. General Provisions

§2701 Definitions

Words not defined in this Chapter shall have their common usage and meaning as stated in the *Merriam-Webster's Collegiate Dictionary – Tenth Edition*, as revised, and other similarly accepted reference texts. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

Administer or *administration* – means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Agent – an individual who acts on behalf or at the direction of a manufacturer, distributor, or other licensee, but does not include a common or contract carrier, public warehouseman, or employee thereof.

Ambulatory Surgical Center or *Surgical Center* – a facility licensed by the department to operate as an ambulatory surgery center.

BNDD – United States Bureau of Narcotics and Dangerous Drugs.

Board – the Louisiana Board of Pharmacy.

Central Fill Pharmacy – a pharmacy which provides centralized dispensing services to other pharmacies, in compliance with the provisions of §1141 of the board's rules.

Certified Animal Euthanasia Technician – an individual authorized by law and certified by the Louisiana State Board of Veterinary Medicine to practice animal euthanasia.

Client Pharmacy – a pharmacy which has engaged the services of a central fill pharmacy.

Controlled Dangerous Substance or *Controlled Substance* – any substance defined, enumerated, or included in federal or state statute or regulations, 21 CFR §1308.11 – 15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled dangerous substance by amendment or supplementation of such regulations or statute. The term shall not include distilled spirits, wine, malt beverages, or tobacco.

CRT – cathode ray tube video display unit.

DEA – United States Drug Enforcement Administration.

Deliver or *Delivery* – the actual, constructive, or attempted transfer of a drug or device containing a controlled substance, from one person to another, whether or not for consideration, or whether or not there exists an agency relationship.

Dentist – an individual authorized by law and licensed by the Louisiana State Board of Dentistry to engage in the practice of dentistry.

Department – the Louisiana Department of Health and Hospitals.

Dispense or *Dispensing* – means the interpretation, evaluation, and implementation of a prescription drug order for a controlled substance, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

Dispenser – an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to dispense drugs or devices containing controlled substances to his own patients in the course of professional practice.

Distribute or *Distributing* – means the delivery of a drug or device containing a controlled substance in response to a non-patient specific purchase order, requisition, or similar communication, other than by administering or dispensing.

Distributor or *Wholesaler* – a facility authorized by law and licensed by the Louisiana State Board of Wholesale Drug Distributors to engage in the distribution of drugs or devices, including controlled substances.

Drug – means: (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 disease in humans or animals, (b) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

disease in humans or animals, or (c) any substance other than food intended to affect the structure or any function of the body of humans or animals.

Drug Detection Canine Trainer – an individual qualified to conduct experiments using controlled substances in training canines to detect the presence of contraband controlled dangerous substances.

Drug Detection Canine Handler – an individual qualified to handle canines in the detection of contraband controlled substances.

Electronic Prescription. A prescription generated, signed, and transmitted in electronic form.

Emergency Clinic – a facility staffed by at least one physician and other licensed medical personnel for the purpose of providing emergency medical treatment.

Facility – an organized health care setting authorized by law and licensed by the department to engage in the provision of health care.

Hospital – a facility licensed by the department to operate as a hospital.

License – means a Louisiana Controlled Dangerous Substances (CDS) License.

Licensee – means an individual or facility in possession of a Louisiana CDS License.

Manufacturer – a person authorized by law and licensed by the federal Food and Drug Administration to engage in the production of drugs, including controlled substances.

Narcotic Treatment Program – a program authorized by law and licensed by the department and the federal Drug Enforcement Administration to operate a substance abuse program using narcotic replacement procedures for individuals dependent upon opium, heroin, morphine, or any other derivative or synthetic drug in that classification of drugs.

Optometrist – an individual authorized by law and licensed by the Louisiana State Board of Optometry Examiners to engage in the practice of optometry.

Person – an individual, corporation, partnership, association, or any other legal entity, including government or governmental subdivision or agency.

Pharmacist – an individual authorized by law and licensed by the board to engage in the practice of pharmacy.

Pharmacy – a place authorized by law and permitted by the board to procure, possess, compound, distribute, and dispense drugs, including controlled substances.

Physician – an individual authorized by law and licensed by the Louisiana State Board of Medical Examiners to engage in the practice of medicine.

Podiatrist – an individual authorized by law and licensed by the Louisiana State Board of Medical Examiners to engage in the practice of podiatry.

Practice Affiliation – a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine, applicable to advanced practice registered nurses and physician assistants.

Practitioner – an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

Prescribe or *Prescribing* – to order a drug or device to be administered or dispensed to a specific patient.

Prescriber – an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe drugs in the course of professional practice.

Prescription or Prescription Drug Order – an order from a practitioner authorized by law to prescribe a drug or device that is patient specific and is to be preserved on file as required by law or regulation.

Researcher – an individual qualified to conduct medical, educational, or scientific experiments on animals, humans, or in laboratories which require the use of controlled substances. For the purpose of this Chapter, manufacturers which use controlled substances in the manufacturing process, but do not manufacture controlled substances as an end product, shall be considered researchers and not manufacturers as defined in R.S. 40:961(24).

Sales Representative or *Professional Medical Representative* – an individual employed by a manufacturer or distributor and authorized by the employer to receive, possess, and deliver controlled substances to a person licensed to possess controlled dangerous substances.

Veterinarian – an individual authorized by law and licensed by the Louisiana State Board of Veterinary Medicine to engage in the practice of veterinary medicine.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2127 (October 2008).

§2703 Controlled Substances

A. Classification

Controlled substances are specifically identified by reference, as provided in R.S. 40:961 *et seq*., or its successor, and 21 CFR §1308 *et seq*., or its successor. Schedules I, II, III, IV, and V shall, unless and until added to pursuant to R.S. 40:961 *et seq*., or its successor, consist of the drugs or other substances, by whatever official name, common or usual name, chemical name, or trade name designated, listed in R.S. 40:961 *et seq*., or its successor.

B. Schedules

Controlled substances are categorized into various schedules based upon the degrees of potential for abuse, as follows:

1. Schedule I
   a. The drug or other substance has a high potential for abuse;
   b. The drug or other substance has no currently accepted medical use in treatment in the United States; and
   c. There is a lack of accepted safety for use of the drug or other substance under medical supervision.
2. Schedule II
   a. The drug or other substance has a high potential for abuse;
   b. The drug or other substance has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions; and
   c. Abuse of the drug or other substance may lead to severe psychological or physical dependence.
   d. When used, Schedule II-N (or 2N) shall refer to the non-narcotic drugs listed in Schedule II.
3. Schedule III
   a. The drug or other substance has a potential for abuse less than the drugs or other substances listed in Schedules I and II;
   b. The drug or other substance has a currently accepted medical use in treatment in the United States; and
   c. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
   d. When used, Schedule III-N (or 3N) shall refer to the non-narcotic drugs listed in Schedule III.
4. Schedule IV
   a. The drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule III;
   b. The drug or other substance has a currently accepted medical use in treatment in the United States; and
   c. Abuse of the drug or other substance may lead to limited psychological or physical dependence relative to the drugs or other substances listed in Schedule III.
5. Schedule V
   a. The drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule IV;
   b. The drug or other substance has a currently accepted medical use in treatment in the United States; and
   c. Abuse of the drug or other substance may lead to limited psychological or physical dependence relative to the drugs or other substances listed in Schedule IV.

C. Scheduling of Additional Controlled Substances

R.S. 40:963 authorizes the Secretary of the department to add additional substances to the schedules identified in Subsection B. In making the determination to add a substance, the Secretary is required to make certain findings, as identified in R.S. 40:963.

1. In determining whether a drug has a "stimulant effect" on the central nervous system, the Secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:
   a. Extended wakefulness;
   b. Elation, exhilaration or euphoria (exaggerated sense of well-being);
   c. Alleviation of fatigue;
   d. Insomnia, irritability, or agitation;
   e. Apprehension or anxiety;
   f. Flight of ideas, loquacity, hypomania or transient delirium.
2. In determining whether a drug has a "depressant effect" on the central nervous system, the Secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:
   a. Calming effect or relief of emotional tension or anxiety;

b. Drowsiness, sedation, sleep, stupor, coma, or general anesthesia;
c. Increase of pain threshold;
d. Mood depression or apathy;
e. Disorientation, confusion or loss of mental acuity.

3. In determining whether a drug is "habit-forming," the Secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:
a. A psychological or physical dependence on the drug (compulsive use);
b. Euphoria;
c. Personality changes;
d. Transient psychoses, delirium, twilight state, or hallucinations;
e. Chronic brain syndrome;
f. Increased tolerance or a need or desire to increase the drug dosage;
g. Physical dependence or a psychic dependence evidenced by a desire to continue taking the drug for a sense of improved well-being that it engenders;
h. Pharmacological activity similar or identical to that of drugs previously designated as habit-forming.

4. In determining whether a drug has a "hallucinogenic effect," the Secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce hallucinations, illusions, delusions, or alteration of any of the following:
a. Orientation with respect to time or place;
b. Consciousness, as evidenced by confused states, dreamlike revivals of past traumatic events or childhood memories;
c. Sensory perception, as evidenced by visual illusions, synesthesia, distortion of space and perspective;
d. Motor coordination;
e. Mood and affectivity, as evidenced by anxiety, euphoria, hypomania, ecstasy, autistic withdrawal;
f. Ideation, as evidenced by flight of ideas, ideas of reference, impairment of concentration and intelligence;
g. Personality, as evidenced by depersonalization and derealization, impairment of conscience and of acquired social and cultural customs.

5. The Secretary may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:
a. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community;
b. There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels;
c. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or
d. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

D. Combination Drugs; Exemption From Certain Requirements

Pursuant to R.S. 40:965, the list of combination drugs and preparations exempted from the application of this Chapter shall be the List of Exempted Prescription Products as identified in the current Code of Federal Regulations, specifically at 21 CFR 1308.32.

E. Excepted Drugs; Exemption From Certain Requirements

Pursuant to R.S. 40:965, the list of excepted drugs and preparations which contain any depressant or stimulant substance listed in Subsections 1, 2, 3, or 4 of Schedule III shall be the List of Exempted Prescription Products as identified in the current Code of Federal Regulations, specifically at 21 CFR 1308.32.

F. Changes in the Schedule of Controlled Substances

Pursuant to changes in the schedule of a controlled substance by either the United States Drug Enforcement Administration or the State of Louisiana, all licensees shall adhere to the more stringent requirement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2128 (October 2008).

§2704. Added Controlled Dangerous Substances

[This section reserved for future use by the Department of Health and Hospitals, for the purpose of emergency scheduling actions for new substances in Schedule I, or for dangerous drug stop orders.]

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:962 and R.S. 40:963.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:1360 (Emergency Rule), effective May 5, 2011. This rule was effectively superseded by Act 420 of 2011 Legislature, which became effective July 15, 2011.

Subchapter B. Licenses

§2705 Licenses and Exemptions

A. Every person who manufactures, distributes, prescribes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of any controlled substance shall obtain a Controlled Dangerous Substance (CDS) License from the board prior to engaging in such activities. Only persons actually engaged in such activities are required to obtain a CDS license; related or affiliated persons, e.g., stockholder in manufacturing corporation, who are not engaged in such activities, are not required to be licensed. The performance of such activities in the absence of a valid CDS license shall be a violation of R.S. 40:973 and these rules.

B. The following persons are exempt from the CDS license requirements of this Chapter:

1. A manufacturer's or distributor's workman, contract carrier, warehouseman or any employee thereof whose handling of controlled substances is in the usual course of his business or employment while on the premises of the employer or under direct transfer orders of the employer.
2. A person who obtains or possesses a controlled substance pursuant to a valid prescription, either for his own use or for the use of a member of his household or for the administration to an animal owned by him or a member of his household.
3. An agent or employee of any licensed manufacturer, distributor, dispenser or researcher in the course of his employment and only on the premises of his employer, but not a sales representative or professional medical representative.

C. Practitioners

1. The issuance of a CDS license to a practitioner, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by a standing professional board in the State of Louisiana or other agency of competent jurisdiction.
2. For the purpose of prescribing controlled substances, a Louisiana CDS license issued to a practitioner shall be valid in any location in Louisiana; however, the procurement and possession of controlled substances shall require a separate CDS license for each such location where controlled substances are possessed.
3. A prescribing practitioner desiring to procure and possess controlled substances at only one location need only obtain a single CDS license.
4. A physician in possession of a valid, verifiable and unrestricted license to practice medicine issued by the Louisiana State Board of Medical Examiners may apply for and be issued a CDS license to authorize the prescribing of the following controlled substances classified in Schedule I: marijuana, tetrahydrocannabinols, and synthetic derivatives of tetrahydrocannabinols; provided however that such prescribing shall only be authorized for therapeutic use by patients clinically diagnosed with glaucoma, spastic quadriplegia, or symptoms resulting from the administration of cancer chemotherapy treatment.

D. Pharmacies

1. The issuance of a CDS license to a pharmacy, and the renewal thereof, shall require the possession of a valid and verifiable permit to operate a pharmacy issued by the board.
2. A Louisiana CDS license issued to a pharmacy shall be valid for the premises identified on the license.
3. The possession of controlled substances under the control of the pharmacy at a different location shall require a separate CDS license for each separate location.

E. Facilities

The issuance of a CDS license to a facility, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by the department, or its successor.

F. Manufacturers and Distributors

1. The issuance of a CDS license to a manufacturer, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of Public Health in the Louisiana Department of Health and Hospitals, or its successor. Further, the applicant shall submit to an initial and periodic inspection by the board or its designee.
2. The issuance of a CDS license to a distributor, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of Public Health in the Louisiana Department of Health and Hospitals, as well as the Louisiana State Board of Wholesale Drug Distributors, or their successors. Further, the applicant shall submit to an initial and periodic inspection by the board or its designee.
3. The sale or transportation of controlled substances within the State of Louisiana by manufacturers and distributors located outside the State of Louisiana shall require the possession of a valid CDS license issued by the board prior to the engagement of such activities.

G. Researchers

1. The issuance of a CDS license to a researcher, and the renewal thereof, shall require the attachment to the application of a properly completed form supplied by the board describing the research, and further, when the research involves human subjects, the attachment to the application of proof of approval by the appropriate Institutional Review Board.
2. A determination of qualification shall be made by the board or its designee.

H. Drug Detection Canine Trainers/Handlers

1. The issuance of a CDS license to a drug detection canine trainer or handler, and the renewal thereof, shall require the attachment to the application of a properly completed form supplied by the board describing the policies and procedures for the use of controlled substances.
2. A determination of qualification shall be made by the board or its designee.
3. This Section shall not apply to a law enforcement agency or its personnel in the performance of its official duties.

I. Certified Animal Euthanasia Technician

The issuance of a CDS license to a certified animal euthanasia technician, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by the Louisiana Board of Veterinary Medicine, or its successor.

J. Professional Medical Representatives

The issuance of a CDS license to professional medical representative, and the renewal thereof, shall require the attachment to the application of written verification of employment from the manufacturer or distributor, as well as their authorization for the representative to receive, possess, and deliver controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2129 (October 2008), amended LR 39:312 (February 2013).

§2707 Licensing Procedures

A. Application for Initial Issuance of CDS License

1. An individual or other entity desiring to obtain a Louisiana CDS license shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 40:972 and R.S. 40:1013, to the board.
2. The applicant shall provide a complete street address reflecting the location where the applicant will engage in the activity for which a Louisiana CDS license is required. The board shall issue only one CDS license for each applicant at each such location.
3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

4. Applicants not in possession of a valid and verifiable license or other credential from a standing professional board of the State of Louisiana, or from the Department of Health and Hospitals, Bureau of Health Services Financing, Health Standards, or their successors, shall submit to a criminal history record check upon request by the board. The applicant shall pay for the cost of the criminal history record check. The board shall evaluate the findings of the report of the criminal history record check prior to the issuance of the CDS license.

5. An individual or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have committed a prohibited act under R.S. 40:961 *et seq.* or its successor.

6. A CDS license shall be valid for a period of one (1) year, and shall expire annually on the date of initial licensure unless revoked sooner in accordance with the provisions of the Uniform Controlled Dangerous Substances Law or these rules.

7. Practitioners in possession of a temporary or restricted license issued by a standing professional board of competent jurisdiction in the State of Louisiana may be issued a temporary or restricted Louisiana CDS license adhering to the limitations or restrictions of their board license.

B. Application for Renewal of CDS License

1. A licensee shall complete the application for renewal of a CDS license and submit same to the board prior to the expiration date of the current license. The application shall be submitted in such form and contain such data and attachments as the board may require and be accompanied by the appropriate fees, as set forth in R.S. 40:972 and R.S. 40:1013.

2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

3. A CDS license not renewed by the expiration date shall be classified as expired. A licensee shall not engage in any activity requiring a valid CDS license while his license is expired.

4. A CDS license not renewed within thirty days following the expiration date shall be automatically terminated by the board. The reissuance of a terminated CDS license shall require compliance with the board's reinstatement procedures.

C. Application for Reinstatement of Terminated, Suspended, or Revoked CDS License

1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee and delinquent fee identified in R.S. 40:972 and the program fee identified in R.S. 40:1013.

2. An application for the reinstatement of a terminated credential which has been expired:

   a. less than one year may be approved by the board's administrative personnel.

   b. more than one year but less than five years may be approved by a member of the board charged with such duties.

   c. more than five years may only be approved by the full board following a hearing to determine whether the reinstatement of the credential is in the public's best interest.

3. An application for the reinstatement of a CDS license suspended or revoked as a consequence of the suspension or revocation of the primary credential by the issuing agency shall require verification of the reinstatement of the primary credential. Where the issuing agency reinstating the primary credential has restricted any privileges for controlled substances, those restrictions shall be attached to the reinstated CDS license. Where the agency reinstating the primary credential has placed that credential on probation for any period of time, the CDS license shall be placed on probation for the same period of time.

4. An application for the reinstatement of a CDS license suspended or revoked by the board may only be approved by the full board following a hearing to determine whether the reinstatement of the license is in the public's best interest.

5. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee as identified at La. R.S. 37:1184.

D. Maintenance of CDS Licenses

1. A CDS license is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than the business location for which it is issued.

2. In order to maintain a CDS license, the applicant shall maintain a federal license required by federal law to engage in the manufacture, distribution, prescribing, or dispensing of controlled substances.

3. The licensee shall inform the board of any and all changes to its business location/address within ten days, with documentation, attesting to any change of business location/address, with notice to include both the old

and new address. A change in business address of a facility may require an inspection by the board or its designee.

4. A duplicate or replacement license shall be issued upon the written request of the licensee and a payment of the fee shall be charged as provided by R.S. 40:972. A duplicate or replacement license shall not serve or be used as an additional or second license.

5. A facility changing ownership shall notify the board in writing 15 calendar days prior to the transfer of ownership.

a. A change of ownership is evident under the following conditions:

i. sale;

ii. death of a sole proprietor;

iii. the addition or deletion of one or more partners in a partnership;

iv. bankruptcy sale; or

v. a fifty (50) percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original CDS license.

b. The new owner(s) shall submit a properly completed application, with all required attachments and appropriate fee, to the board.

c. Upon the receipt of the new CDS license, the previous licensee shall:

i. notify the board of the transaction, including the identity of the new owner(s); and

ii. surrender his CDS license to the board.

d. A CDS license is not transferable from the original owner to a new owner.

e. A change in ownership may require an inspection by the board or its designee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2131 (October 2008).

§2709 Actions on Applications

A. Upon receipt of a properly completed application and appropriate fees from a qualified applicant, the board shall issue a Louisiana CDS license to the applicant, unless the board intends to deny the application.

B. The board may deny an application for the issuance or renewal of a CDS License for cause. For purposes of this Section, the term "for cause" includes surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2132 (October 2008).

§2711 Actions on Licenses

A. The board may refuse to renew a CDS license, or may suspend or revoke an existing CDS license, if the licensee has violated, or been found guilty of violating, any federal or state laws or regulations relating to controlled substances.

B. Violations Committee

1. Informal Hearings

The violations committee of the board may conduct an informal non-adversarial hearing with a licensee properly noticed of the inquiry regarding the issues to be discussed. The committee shall receive information and deliberate as to a cause of action regarding a potential violation. By an affirmative majority vote of the committee members, they may recommend a course of action to the full board, or they may dismiss the allegations. Should the committee recommend a course of action to the full board, the committee members participating in that decision shall not be permitted to participate in subsequent formal administrative hearings pertaining to the complaint or alleged violation(s) heard by the committee, unless the licensee allows otherwise.

2. Interlocutory Hearings

By interlocutory, or summary, hearing, the committee may summarily suspend a CDS license prior to a formal administrative board hearing wherein, based upon the committee's judgment and reflected by adequate evidence and an affirmative majority decision, the licensee poses a danger to the public's health, safety, and welfare, and the danger requires emergency action.

1. Summons Notice. A summary proceeding summons notice shall be served at least five days before the scheduled hearing to afford the licensee an opportunity to be heard with respect to a potential summary suspension action. The notice shall contain a time, place, nature, and the grounds asserted relative to the alleged conduct warranting summary suspension.
2. Burden of Proof. Legal counsel shall have the burden of proof to support the contention the public's health, safety, or welfare is in danger and requires summary or emergency action.
3. Evidence. The licensee shall have the right to appear personally, to be represented by counsel, or both, to submit affidavits, documentary evidence, or testimony in response to the cause of action asserted as the basis for the summary suspension.
4. Decision. The committee shall determine whether to grant or deny the request for summary suspension based upon adequate evidence with an affirmative majority vote substantiated by findings(s) of fact and conclusion(s) of law the public's health, safety, or welfare is in danger and requires emergency or summary action.
5. Report. The committee shall submit their findings and interlocutory decree to the board when rendered.
6. Suspensive Duration. The summary suspension decree shall be followed by a formal administrative hearing within thirty days from receipt of notice by the licensee.

C. Consent Agreements.
A licensee may enter into a consent agreement with the board on any matter pending before the board. A consent agreement is not final until the board approves the consent agreement by an affirmative majority vote of the board. If the consent agreement is rejected in full or part, the matter shall be heard at the next regularly scheduled formal administrative hearing. However, nothing herein shall be construed to limit the board from modifying a consent agreement, with the licensee's approval, to include less severe sanctions than those originally agreed to in a pending consent agreement.

D. Formal Administrative Hearing.
1. Authority. The board shall convene a formal administrative hearing pertaining to the ability to hold a CDS license, in accordance with the Administrative Procedure Act, R.S. 49:950 *et seq*., with authority to take disciplinary action pursuant to R.S. 40:975.
2. Ex-Parte Communication. Once a formal administrative hearing has been initiated and notice served, board members participating in the decision process shall not communicate with a licensee or a licensee's attorney concerning any issue of fact or law involved in the formal administrative hearing.
3. Notice. A formal administrative hearing may be initiated upon proper notice to a licensee and held at a designated time and place based upon the following grounds:
   a. Violation. Sufficient evidence or a serious complaint of an alleged violation to require a formal hearing shall be directed to legal or special counsel for administrative prosecution to justify a formal hearing;
   b. Failure to Respond. A failure by the licensee to respond to a violations committee informal hearing;
   c. Irresolvable Issues. A violations committee informal hearing failed to resolve all issues and requires further formal action;
   d. Irreconcilable Issues. An interlocutory hearing failed to resolve all pertinent pending issues thus requiring further formal action; or
   e. Reaffirmation. Reaffirmation of an interlocutory decree.
   f. Requirement. A formal administrative hearing is required.

E. Formal Administrative Hearing Procedures.
1. Hearing Officer. The presiding hearing officer may be the board president, a vice-president, or other individual appointed by the president or his successor. The hearing officer shall have the responsibility to conduct a fair and impartial proceeding with the administrative duty as well as the authority to:
   a. convene a formal administrative hearing;
   b. rule on motions and procedural questions arising during the hearing such as objections or admissibility of evidence or examination of witnesses;
   c. issue or direct staff to issue subpoenas;
   d. declare recess;
   e. maintain order;
   f. enforce a standard of conduct to insure a fair and orderly hearing; and
   g. remove any disruptive person from the hearing.
2. Oaths. The presiding hearing officer, executive director, or other board designee may administer oaths.

3. Jury. The board, comprised of a quorum of members, shall serve as an administrative jury to hear and determine the disposition of the pending matter based on the finding(s) of fact and conclusion(s) of law by receiving evidence and reaching a decision and ordering sanctions by an affirmative majority record vote of board members participating in the decision process.

4. Hearing Clerk. The board's executive director shall serve as the hearing clerk and shall maintain hearing records.

5. Prosecutor. The legal or special counsel shall prosecute the pending matter.

6. Recorder. The board-designated stenographer shall record all testimony dictated and evidence received at the hearing. The utilization of recording equipment may be employed.

7. Agenda.
   a. Docket. Contested matters shall be identified by reference docket number and caption title.
   b. Complaint. The complaint may be read, unless waived by the licensee.

8. Order
   a. Opening Statements.
      An opening statement by legal or special counsel may present a brief position comment with an outline of evidence to be offered. The licensee or licensee's legal counsel may present an opening defense position statement.
   b. Evidence
      i. Testimony Received. Testimony shall be received under oath administered by the presiding hearing officer, the executive director, or other staff or board member designated by the hearing officer.
      ii. Evidence Introduction. All parties shall be afforded an opportunity to present evidence on all issues of fact and argue on all issues of law and respond by direct testimony, followed with cross examination as may be required for a full and true disclosure of the facts. The direct presentation of evidence shall be introduced by the legal or special counsel and shall be followed by the licensee, either in proper person or by legal counsel, by direct cross-examination or rebuttal, or any combination thereof.
      iii. Examination. Witnesses may be directly examined and cross-examined. Additionally, witnesses and licensees may be questioned by members of the jury on matters for clarification.
      iv. Rule Interpretation. Liberal rules of evidence shall be employed by the presiding hearing officer to provide adequate facts and law necessary for the board to deliberate and decide each case. The board's formal administrative hearing shall not be bound to strict rules of evidence.
      v. Admissibility. Admissibility of evidence and testimony shall be determined by the presiding hearing officer as provided by law.
   c. Closing Arguments
      Closing arguments may be made by the licensee, either in proper person or by legal counsel, followed by closing arguments from the prosecuting legal or special counsel.
   d. Board Decision
      The board's decision shall be based on finding(s) of fact and conclusion(s) of law. The board's decision shall be based on a preponderance of the evidence presented at a formal administrative hearing, together with the board's determination of appropriate sanctions, if any, by an affirmative majority record vote of the board members participating in the decision process. Decisions shall be recorded and made part of the record.
      i. Board Order. The board's order shall be rendered at the formal administrative hearing or taken under advisement and rendered within thirty days after the hearing and then served personally or domiciliary at the licensee's last known address by regular, registered, or certified mail, or by diligent attempt thereof.
      ii. Finality of Board Order. The board's order shall become final and effective eleven days after licensee's receipt of the board's notice of its decision, provided an appeal is not filed.

F. Complaint Dismissal.

The board may, in its discretion and based upon insufficiency of evidence, orally dismiss a pending matter, or parts thereof, at a formal administrative hearing.

G. Transcripts.

A complete record of all formal administrative hearing proceedings shall be transcribed, maintained, and available upon written request for a minimum of three years after the date the pertinent board order is final. The board may require the advance payment of the appropriate fees to cover the cost of preparation of the requested transcript.

H. Contempt.

The failure of a licensee or witness to comply with a board order, after being duly served, constitutes contempt and the board may petition a court of competent jurisdiction to rule the witness or licensee in court to show cause why he should not be held in contempt of court.

I. Rehearing

1. An aggrieved licensee may file a motion for rehearing in proper form, within ten days, requesting reconsideration or a rehearing by the board or by the interlocutory hearing panel.
2. Grounds. The board or an interlocutory hearing panel may consider the motion for rehearing at the next regularly scheduled board meeting. The motion shall allege one or more of the following:
   a. The board's decision was clearly contrary to the law or evidence;
   b. Newly discovered evidence not available at the time of the hearing which may be sufficient to reverse the board's decision;
   c. Issues not previously considered need to be examined; or
   d. It is in the public interest to reconsider the issues and the evidence.
3. Time. The board or the hearing officer shall grant or deny the motion for rehearing within thirty days after its submission.

J. Judicial Review.

An aggrieved licensee may appeal the board's decision to a court of competent jurisdiction within thirty days from the entry of the board order or the denial of the rehearing motion.

K. Cease and desist orders; injunctive relief

1. The board is empowered to issue an order to any person or facility engaged in any activity, conduct, or practice constituting a violation of the R.S. 40:972 *et seq.* or the regulations promulgated thereto, directing such person or facility to forthwith cease and desist from such activity, conduct, or practice.
2. If the person or facility to which the board directs a cease and desist order does not cease and desist the prohibited activity, conduct, or practice within the timeframe directed by said order, the board may seek, in any court of competent jurisdiction and proper venue, a writ of injunction enjoining such person or facility from engaging in such activity, conduct, or practice.
3. Upon proper showing of the board such person or facility has engaged in the prohibited activity, conduct, or practice, the court shall issue a temporary restraining order prohibiting the person or facility from engaging in the activity, conduct, or practices complained of, pending the hearing on a preliminary injunction, and in due course a permanent injunction shall be issued after a contradictory hearing, commanding the cessation of the finally determined unlawful activity, conduct, or practices identified in the complaint.

L. Reinstatement or re-issuance of CDS License.

1. At any time after the suspension or revocation of a CDS license, the board may reinstate the license, but only at an official meeting of the board, after written notice, and by vote of an affirmative majority of the members of the board present and voting. In the event a license is reinstated or reissued following previously applied sanctions relative to a violation of this Chapter, said reinstatement or re-issuance shall have affixed thereto an attachment or addendum, specifically setting forth any restrictions placed upon said reinstated or reissued license by the board.
2. In case of reinstatement, the reinstated licensee shall pay all applicable costs or fines, or both, and a reinstatement fee as provided for in the board's fee schedule established pursuant to R.S. 37:1184 and 40:972.

M. Surrender of License

1. Any person or facility holding a valid CDS license which ceases to engage in activity requiring a CDS license shall surrender said license to the board upon termination of this activity.
2. Upon the surrender of said license, the person or facility shall forward all controlled substances and any unused order forms in his possession or under his control to the United State Drug Enforcement Administration as provided by federal laws and regulations.
3. In the event a person or facility surrenders his DEA Registration to the DEA, then the person or facility shall surrender his CDS license immediately to the board.
4. The acceptance of the voluntary surrender of a CDS license by the board shall result in the automatic suspension of the CDS license for an indefinite period of time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2132 (October 2008).

Subchapter C. Security Requirements

§2713 General Requirements

A. A licensee shall provide effective controls and procedures to guard against theft or diversion of controlled substances. In evaluating the overall security system of a licensee or applicant, the board may consider any of the following factors:

1. the type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
2. the type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
3. the quantity of controlled substances handled;
4. the physical location of the premises;
5. the type of building construction comprising the facility and the general characteristics of the building(s);
6. the type of vault, safe, and secure enclosures or other storage system(s) used;
7. the adequacy of key control systems, combination lock control systems, or both;
8. the adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
9. the extent of unsupervised public and visitor access to the facility including maintenance personnel and non-employee service personnel;
10. the adequacy of supervision of employee access;
11. local police protection or security personnel;
12. the adequacy for monitoring the receipt, manufacture, distribution, procurement, and disposition of controlled substances; and
13. the applicability of the security requirements contained in all federal, state, and local laws and regulations governing the management of waste.

B. When physical security controls become inadequate, the physical security controls shall be expanded and extended accordingly.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2134 (October 2008).

§2715 Physical Security Controls for Non-Practitioners, Narcotic Treatment Programs, and Compounders for Narcotic Treatment Programs

A. Storage Areas

1. Schedules I and II. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas:
    a. Where small quantities permit, a safe or steel cabinet;
        i. which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
        ii. which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it cannot be readily removed; and
        iii. which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.
    b. A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
    c. A vault constructed after September 1, 1971:

i. the walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

ii. the door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

iii. which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

iv. the walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve, and, if necessary, alarm buttons at strategic points of entry to the perimeter area of the vault;

v. the door of which vault is equipped with contact switches; and

vi. which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the board or its designee.

2. Schedules III, IV and V. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in one of the following secure storage areas:

a. a safe or steel cabinet as described in this Section;

b. a vault as described in this Section equipped with an alarm system as described in this Section;

c. a building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

i. has an electronic alarm system as described in this Section,

ii. is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the licensee is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) in the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) in the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

d. a cage, located within a building on the premises, meeting the following specifications:

i. having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) at least one inch in diameter;

(b) set in concrete or installed with lag bolts which are pinned or brazed; and

(c) placed no more than ten feet apart with horizontal one and one-half inch reinforcements every 60 inches;

ii. having a mesh construction with openings of not more than two and one-half inches across the square;

iii. having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height;

iv. is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all federal requirements; and

v. is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the licensee, or to such other source of protection as the board or its designee may approve;

e. an enclosure of masonry or other material, approved in writing by the board or its designee as

providing security comparable to a cage;

f. a building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, the United States Bureau of Narcotics and Dangerous Drugs, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated; or

g. such other secure storage areas as may be approved by the board after considering the factors listed in §2713 of this Chapter.

3. Mixing of Schedules

a. Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by this Section.

b. Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by this Section, provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered shall be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

4. Multiple Storage Areas. Where several types or classes of controlled substances are handled separately by the licensee or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided each storage area complies with the requirements set forth in this Section.

5. Accessibility to Storage Areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the licensee shall provide for adequate observation of the area by an employee specifically authorized in writing.

B. Manufacturing and Compounding Areas

1. Before distributing a controlled substance to any person who the licensee does not know to be registered to possess the controlled substance, the licensee shall make a good faith inquiry, either with the DEA or the board, to determine that the recipient is registered to possess the controlled dangerous substance.

2. All manufacturing and compounding activities (including processing, packaging and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

a. All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked. If security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee.

b. Manufacturing activities with controlled substances shall be conducted in an area of clearly defined limited access under surveillance by an employee(s) designated in writing as responsible for the area. Limited access may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated responsible for the area may be engaged in the particular manufacturing operation being conducted, provided he is able to provide continuous surveillance of the area to ensure unauthorized individuals do not enter or leave the area without his knowledge.

c. During the production of controlled substances, the manufacturing areas shall be accessible only to those employees required for efficient operation. When employee maintenance personnel, non employee maintenance personnel, business guests, or visitors are present during production of controlled substances, the licensee shall provide for adequate observation of the area by an employee specifically authorized in writing.

C. Other Requirements/Narcotic Treatment Programs

1. Before distributing a controlled substance to any person who the licensee does not know to be registered to possess the controlled substance, the licensee shall make a good faith inquiry either with the DEA or the board to determine that the person is registered to possess the controlled substance.

2. The licensee shall design and operate a system to disclose to the licensee suspicious orders of controlled substances. The licensee shall inform the New Orleans Field Division Office of the DEA, or its successor, of suspicious orders when discovered by the licensee. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

3. a. The licensee shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer:
   i. without the prior written request of the customer;
   ii. to be used only for satisfying the legitimate medical needs of patients of the customer; and
   iii. only in reasonable quantities.

   b. Such request shall contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the licensee with other records of distribution of controlled substances. In addition, the procurement requirements of §2743 of this Chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

4. When shipping controlled substances, a licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a licensee is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in §2715.A of this Chapter. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

5. When distributing controlled substances through agents (e.g., sales representatives), a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled.

6. Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the licensee shall verify that the person is authorized to handle the substances(s) by contacting the DEA.

7. The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

8. Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either:
   a. the licensed practitioner;
   b. a registered nurse under the direction of the licensed practitioner;
   c. a licensed practical nurse under the direction of the licensed practitioner; or
   d. a pharmacist under the direction of the licensed practitioner.

9. Persons enrolled in a narcotic treatment program shall be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

10. All narcotic treatment programs shall comply with standards established by the department respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

11. The board may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2135 (October 2008).

§2717 Physical Security Controls for Practitioners and Pharmacies

A. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

B. Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

C. This section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration.

D. Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

E. The licensee shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" includes surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

F. The licensee shall notify the board and the Field Division Office of the DEA in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The licensee shall also complete, and submit to the board and the Field Division Office of the DEA in his area, DEA Form 106, or its electronic equivalent, regarding the loss or theft. When determining whether a loss is significant, a licensee should consider, among others, the following factors:

1. the actual quantity of controlled substances lost in relation to the type of business;
2. the specific controlled substances lost;
3. whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. whether the specific controlled substances are likely candidates for diversion;
6. local trends and other indicators of the diversion potential of the missing controlled substance.

G. Whenever the licensee distributes a controlled substance (without being registered as a distributor, as permitted by law) he shall comply with the requirements imposed on non-practitioners.

H. Central fill pharmacies shall comply with federal and state law when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106 or its electronic equivalent. Retail pharmacies shall comply with federal and state law when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106 or its electronic equivalent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2137 (October 2008).

§2719 Security Controls for Freight Forwarding Facilities

A. All Schedule II-V controlled substances that will be temporarily stored at the freight forwarding facility shall be either:

1. stored in a segregated area under constant observation by designated responsible individual(s); or
2. stored in a secured area that meets the requirements of this Chapter. For purposes of this requirement, a facility that may be locked down (i.e., secured against physical entry in a manner consistent with requirements of this part) and has a monitored alarm system or is subject to continuous monitoring by security personnel will be deemed to meet the requirements of this Chapter.

B. Access to controlled substances shall be kept to an absolute minimum number of specifically authorized individuals. Non-authorized individuals may not be present in or pass through controlled substances storage areas without adequate observation provided by an individual authorized in writing by the licensee.

C. Controlled substances being transferred through a freight forwarding facility shall be packed in sealed, unmarked shipping containers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2138 (October 2008).

§2721 Employee Screening by Non-Practitioners

A. An employer's comprehensive employee screening program shall include the following:

1. Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.
2. Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician or other authorized prescriber? If the answer is yes, furnish details.
3. Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions shall be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person shall be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2138 (October 2008).

Subchapter D. Labeling and Packaging Requirements

§2723 Symbol Required

A. Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, shall bear a label complying with the requirement of this Section.

B. Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

C. The following symbols shall designate the schedule corresponding thereto:

Schedule	
Schedule I	CI or C-I
Schedule II	CII or C-II
Schedule III	CIII or C-III
Schedule IV	CIV or C-IV
Schedule V	CV or C-V

The word "schedule" need not be used. No distinction need be made between narcotic and non-narcotic substances.

D. The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.

E. The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.
F. The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2138 (October 2008).

§2725 Location and Size of Symbol on Label and Labeling

A. The symbol shall be prominently located on the label or the labeling of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance. The symbol on labels shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf. The symbol on all other labeling shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

§2727 Sealing of Controlled Substances

A. On each bottle, multiple dose vial, or other commercial container of any controlled substance, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

§2729 Labeling and Packaging Requirements for Imported and Exported Controlled Substances

A. The symbol requirements of this Section apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of Louisiana.

B. The symbol requirements of this Section do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from Louisiana.

C. The sealing requirements of this Section apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or any narcotic controlled substance listed in schedule III or IV, imported into, exported from, or intended for export from, Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

Subchapter E. Recordkeeping Requirements

§2731 General Information

A. Persons Required to Keep Records and File Reports
   1. Each licensee shall maintain the records and inventories and shall file the reports required by this Chapter, except as exempted by this Section. Any licensee who is authorized to conduct other activities without being registered to conduct those activities by federal law shall maintain the records and inventories and shall file the

reports required by this Section for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor does it require that separate records are required for each activity. Thus, when a researcher manufactures a controlled item, he shall keep a record of the quantity manufactured; when he distributes a quantity of the item, he shall use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

2. An individual practitioner is required to keep records of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

3. An individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

4. An individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

5. Each registered mid-level practitioner shall maintain in a readily retrievable manner those documents required by the state in which he practices which describe the conditions and extent of his authorization to dispense or distribute controlled substances and shall make such documents available for inspection and copying by authorized agents of the board. Examples of such documentation include protocols, practice guidelines or practice agreements.

6. Licensees using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under Section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections, are not required to keep records if he notifies the DEA and the board of the name, address, and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for a CDS license or his renewal and shall be made in the form of an attachment to the application, which shall be filed with the application.

7. A distributing licensee who utilizes a freight forwarding facility shall maintain records to reflect transfer of controlled substances through the facility. These records shall contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. A distributing licensee may, as part of the initial request to operate a freight forwarding facility, request permission to store records at a central location. Approval of the request to maintain central records would be implicit in the approval of the request to operate the facility. Otherwise, a request to maintain records at a central location shall be submitted in accordance with this Section. These records shall be maintained for a period of two years.

8. With respect to any and all records required by this Chapter which are maintained in a language other than English, the person responsible for maintaining such records shall provide a document accurately translating such records to English within 72 hours of such request by the board or an agent of the board.

B. Maintenance of Records and Inventories

1. Except as otherwise provided in this Section, every inventory and other records required to be kept under this Section shall be kept by the licensee and be available, for at least two years from the date of such inventory or records, for inspection and copying by authorized employees of the board.

   a. Financial and shipping records may be kept at a central location, rather than at the registered location, if the licensee has notified the board in writing of his intention to keep central records. All notifications shall include the following:

      i. the nature of the records to be kept centrally.

      ii. the exact location where the records will be kept.

iii. the name, address, DEA registration number and type of DEA registration of the licensee whose records are being maintained centrally.

iv. whether central records will be maintained in a manual, or computer readable, form.

b. A pharmacy which possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this Section for those additional registered sites at the pharmacy or other approved central location.

2. All licensees authorized to maintain a central recordkeeping system shall be subject to the following conditions:

a. The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

b. If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the licensee shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

c. The licensee agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the board for such records, and if the board chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the board to inspect such records at the central location upon request by such employees without a warrant of any kind.

d. In the event that a licensee fails to comply with these conditions, the board may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the licensee without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the licensee shall, within the time specified by the board, comply with the requirements of this Section that all records be kept at the registered location.

3. Licensees need not notify the board or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

4. ARCOS participants who desire authorization to report from other than their registered locations shall obtain a separate central reporting identifier. Request for central reporting identifiers shall be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

5. Each manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

a. inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the other records of the licensee; and

b. inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the licensee or in such form that the information required is readily retrievable from the ordinary business records of the licensee.

6. Each individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in this Section.

7. Each pharmacy shall maintain the inventories and records of controlled substances as follows:

a. inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

b. inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Records of Authorized Central Fill Pharmacies and Client Pharmacies

1. Every pharmacy that utilizes the services of a central fill pharmacy shall keep a record of all central

fill pharmacies, including name, address and DEA number, which are authorized to fill prescriptions on its behalf. The pharmacy shall also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records shall be made available upon request for inspection by the board.

2. Every central fill pharmacy shall keep a record of all pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy shall also verify the registration for all pharmacies for which it is authorized to fill prescriptions. These records shall be made available upon request for inspection by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

§2733 Inventory Requirements

A. General Requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device shall be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the licensee, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the licensee, and substances in the possession of employees of the licensee and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in this Section. In the event controlled substances in the possession or under the control of the licensee are stored at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and that option shall be indicated on the inventory.

B. Initial Inventory Date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with this Section as applicable. In the event a person commences business with no controlled substances on hand, he shall record this fact as the initial inventory.

C. Biennial Inventory Date. After the initial inventory is taken, the licensee shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

1. Exception.
   a. Pharmacies shall take a new inventory of all stocks of controlled substances on hand every year; the annual inventory may be taken on any date which is within one year of the previous annual inventory date.
   b. Pharmacies shall take a new inventory on the following occasions:
      i. arrival of a new pharmacist-in-charge;
      ii. discovery of any substantial loss, disappearance, or theft of controlled substances;
      iii. departure of a pharmacist-in-charge; and
      iv. permanent closure of a pharmacy.

D. Inventories of Manufacturers, Distributors, Dispensers, Researchers, Importers, Exporters, and Chemical Analysts. Each person registered or authorized to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records shall include in the inventory the information listed below.

1. Inventories of Manufacturers.

   Each person authorized to manufacture controlled substances shall include the following information in the inventory:
   a. For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:
      i. the name of the substance; and
      ii. the total quantity of the substance to the nearest metric unit weight consistent with unit size.
   b. For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:
      i. the name of the substance;

ii. the quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

iii. the physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

c. For each controlled substance in finished form the inventory shall include:

i. the name of the substance;

ii. each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

iii. the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

iv. the number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

d. For each controlled substance not included in this Section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding) the inventories shall include:

i. the name of the substance;

ii. the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

iii. the reason for the substance being maintained by the licensee and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

2. Inventories of Distributors.

Except for reverse distributors covered in this Section, each person authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section.

3. Inventories of Dispensers, Researchers, and Reverse Distributors.

Each person authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

a. if the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

b. if the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he shall make an exact count of the contents.

4. Inventories of Importers and Exporters.

Each person authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section. Each such person who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

5. Inventories of Chemical Analysts.

Each person authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to this Section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2141 (October 2008).

§2735 Continuing Records

A. General Requirements

1. Every licensee required to keep records pursuant to this Section shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him.
2. Separate records shall be maintained by a licensee for each registered location except as provided in §2731.B. In the event controlled substances are in the possession or under the control of a licensee at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.
3. Separate records shall be maintained by a licensee for each independent activity for which he is registered, except as provided in Subsection B of this Section.
4. In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

B. Records for Manufacturers, Distributors, Dispensers, Researchers, Importers, and Exporters

1. Records for Manufacturers. Each person authorized to manufacture controlled substances shall maintain records with the following information:

a. For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or non-controlled substances in finished form,

i. the name of the substance;

ii. the quantity manufactured in bulk form by the licensee, including the date, quantity and batch or other identifying number of each batch manufactured;

iii. the quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

iv. the quantity imported directly by the licensee (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

v. the quantity used to manufacture the same substance in finished form, including:

(a) the date and batch or other identifying number of each manufacture;

(b) the quantity used in the manufacture;

(c) the finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(d) the number of units of finished form manufactured;

(e) the quantity used in quality control;

(f) the quantity lost during manufacturing and the causes therefore, if known;

(g) the total quantity of the substance contained in the finished form;

(h) the theoretical and actual yields; and

(i) such other information as is necessary to account for all controlled substances used in the manufacturing process;

vi. the quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required in Clause B.1.a.v of this Section;

vii. the quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

viii. the quantity exported directly by the licensee (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

ix. the quantity distributed or disposed of in any other manner by the licensee (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and

x. the originals of all written certifications of available procurement quotas submitted by other persons as required by federal law relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

b. For each controlled substance in finished form:

i. the name of the substance;

ii. each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

iii. the number of containers of each such commercial finished form manufactured from bulk form by the licensee, including the information required pursuant Clause B.1.a.v of this Section;

iv. the number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;

v. the number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

vi. the number of units and/or commercial containers manufactured by the licensee from units in finished form received from others or imported, including:

(a) the date and batch or other identifying number of each manufacture;

(b) the operation performed (e.g., repackaging or relabeling);

(c) the number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(d) such other information as is necessary to account for all controlled substances used in the manufacturing process;

vii. the number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;

viii. the number of commercial containers exported directly by the licensee (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

ix. the number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the licensee (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

2. Records for Distributors. Each person authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section.

3. Records for Dispensers and Researchers. Each person authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription shall also comply with federal law.

4. Records for Importers and Exporters. Each person authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section. In addition, the quantity disposed of in any other manner by the licensee (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to this Section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to this Section.

C. Records for Chemical Analysts

1. Each person authorized to conduct chemical analysis with controlled substances shall maintain records with the following information for each controlled substance:

a. the name of the substance;

b. the form or forms in which the substance is received, imported, or manufactured by the licensee (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram tablet or 10-milligram concentration per milliliter);

c. the total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and DEA registration number, if any, of the person from whom the substance was received;

d. the quantity distributed, exported, or destroyed in any manner by the licensee (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and DEA registration number, if any, of each person to whom the substance was distributed or exported.

2. Records of controlled substances used in chemical analysis or other laboratory work are not required.

3. Records relating to known or suspected controlled substances received as evidentiary material for analysis are not required by this Section.

D. Records for Narcotic Treatment Programs

1. Each person authorized by federal and state law to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

a. name of substance;
b. strength of substance;
c. dosage form;
d. date dispensed;
e. adequate identification of patient (consumer);
f. amount consumed;
g. amount and dosage form taken home by patient; and
h. dispenser's initials.

2. The records required by this Section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with Subsection B of this Section.

3. All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use shall keep a separate batch record of the compounding.

4. Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by law.

E. Records for Compounders for Narcotic Treatment Programs

Each person authorized to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information:

1. for each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other non-controlled substances in finished form:

a. the name of the substance;
b. the quantity compounded in bulk form by the licensee, including the date, quantity and batch or other identifying number of each batch compounded;
c. the quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;
d. the quantity imported directly by the licensee (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;
e. the quantity used to compound the same substance in finished form, including:
   i. the date and batch or other identifying number of each compounding;
   ii. the quantity used in the compound;
   iii. the finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);
   iv. the number of units of finished form compounded;
   v. the quantity used in quality control;
   vi. the quantity lost during compounding and the causes therefore, if known;
   vii. the total quantity of the substance contained in the finished form;
   viii. the theoretical and actual yields; and
   ix such other information as is necessary to account for all controlled substances used in the compounding process;
f. the quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in Clause B.1.a.v of this Section;
g. the quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;

h. the quantity exported directly by the licensee (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exploration; and
i. the quantity disposed of by destruction, including the reason, date and manner of destruction.

2. for each narcotic controlled substance in finished form:
   a. the name of the substance;
   b. each finished form (e.g., 10-milligram tablet or 10 milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
   c. the number of containers of each such commercial finished form compounded from bulk form by the licensee, including the information required pursuant to Clause B.1.a.v of this Section;
   d. the number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;
   e. the number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;
   f. the number of units and/or commercial containers compounded by the licensee from units in finished form received from others or imported, including:
      i. the date and batch or other identifying number of each compounding;
      ii. the operation performed (e.g., repackaging or relabeling);
      iii. the number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and
      iv. such other information as is necessary to account for all controlled substances used in the compounding process;
   g. the number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to which the containers were distributed;
   h. the number of commercial containers exported directly by the licensee (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and
   i. The number of units of finished forms and/or commercial containers destroyed in any manner by the licensee, including the reason, the date and manner of destruction.

F. Additional Recordkeeping Requirements Applicable to Drug Products Containing Gamma-Hydroxybutyric Acid
In addition to the recordkeeping requirements for dispensers and researchers provided in this Chapter, practitioners dispensing gamma-hydroxybutyric acid manufactured or distributed in accordance with federal law shall maintain and make available for inspection and copying by the board, all of the following information for each prescription:
1. name of the prescribing practitioner.
2. prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations.
3. verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.
4. patient's name and address.
5. patient's insurance provider, if available.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2142 (October 2008).

§2737 Reports

A. Reports from Manufacturers Importing Narcotic Raw Material
1. Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted in compliance with 21 CFR §1304.31or its successor.

2. The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):
   a. beginning inventory;
   b. gains on reweighing;
   c. imports;
   d. other receipts;
   e. quantity put into process;
   f. losses on reweighing;
   g. other dispositions; and
   h. ending inventory.
3. The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):
   a. beginning inventory;
   b. gains on reweighing;
   c. quantity extracted from narcotic raw material;
   d. quantity produced/manufactured/synthesized;
   e. quantity sold;
   f. quantity returned to conversion processes for reworking;
   g. quantity used for conversion;
   h. quantity placed in process;
   i. other dispositions;
   j. losses on reweighing; and
   k. ending inventory.
4. The following information shall be submitted for importation of each narcotic raw material:
   a. import permit number;
   b. date shipment arrived at the United States port of entry;
   c. actual quantity shipped;
   d. assay (percent) of morphine, codeine and thebaine; and
   e. quantity shipped, expressed as anhydrous morphine alkaloid.
5. Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.
6. Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.
7. All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it shall no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

B. Reports from Manufacturers Importing Coca Leaves

1. Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted in compliance with 21 CFR §1304.32.
2. The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):
   a. beginning inventory;
   b. imports;
   c. gains on reweighing;
   d. quantity purchased;
   e. quantity produced;
   f. other receipts;

g. quantity returned to processes for reworking;
h. material used in purification for sale;
i. material used for manufacture or production;
j. losses on reweighing;
k. material used for conversion;
l. other dispositions; and
m. ending inventory.

3. The following information shall be submitted for importation of coca leaves:
   a. import permit number;
   b. date the shipment arrived at the United States port of entry;
   c. actual quantity shipped;
   d. assay (percent) of cocaine alkaloid; and
   e. total cocaine alkaloid content.

4. Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

5. Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

6. All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it shall no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

C. Reports to ARCOS

1. Reports generally. All reports required by this Subsection shall be filed with the ARCOS Unit, PO 28293, Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit. A copy of the report shall be filed with the board.

2. Frequency of Reports. Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a licensee may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that licensee. Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing. These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a licensee may be given permission to file more frequently (but not more frequently than quarterly).

3. Persons Reporting. For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III and gamma- hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in Paragraph 4 of this Subsection.

4. Substances Covered.
   a. Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:
      i. Schedule III

(a) benzphetamine;
(b) cyclobarbital;
(c) methyprylon; and
(d) phendimetrazine.

ii. Schedule IV
(a) barbital;
(b) diethylpropion (amfepramone);
(c) ethchlorvynol;
(d) ethinamate;
(e) lefetamine (SPA);
(f) mazindol;
(g) meprobamate;
(h) methylphenobarbital;
(i) phenobarbital;
(j) phentermine; and
(k) pipradrol.

b. Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

5. Transactions reported. Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

6. Exceptions. A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the licensee may be exempted from filing reports under this section by applying to the ARCOS Unit of the DEA.

D. Reports of Theft or Loss

The licensee shall notify the New Orleans Field Division Office of the DEA, or its successor, and the board, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of such theft or loss. The supplier is responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Subsection E of this Section, within one business day of discovery of such theft or loss. The licensee shall also complete, and submit to the New Orleans Field Division Office of the DEA, or its successor, and the board, DEA Form 106, or its electronic equivalent, regarding the theft or loss. Thefts and significant losses shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a licensee should consider, among others, the following factors:

1. the actual quantity of controlled substances lost in relation to the type of business;
2. the specific controlled substances lost;
3. whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. whether the specific controlled substances are likely candidates for diversion; and
6. local trends and other indicators of the diversion potential of the missing controlled substance.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2145 (October 2008).

Subchapter F. Production, Distribution and Utilization

§2739 Manufacture

A. A licensee located in Louisiana engaged in the manufacture of controlled dangerous substances within Schedules I, II, III, IV, or V shall prepare a complete and accurate record of the date of manufacture, the theoretical and actual yields, the quantity used for quality control, the identity of batch numbers or other appropriate identification, and the quantity of any product reworked for any reason for each manufactured batch of controlled dangerous substances or each manufactured batch of drugs in which a controlled dangerous substance was used as a raw material.

B. The licensee shall maintain manufacturing records in such a manner that the identity of a batch of controlled dangerous substances finished product can be matched to the identity of the controlled dangerous substance raw material used to make that product.

C. The licensee shall maintain any other such records as are necessary to account for all controlled dangerous substances used in the manufacturing process.

D. A building where manufacturing takes place shall be maintained in a clean and orderly manner and shall be of a suitable size, construction, and location to facilitate cleaning, maintenance, processing, and packing, labeling, or storing of legend drugs pursuant to federal and state requirements.

E. All manufacturers shall employ security precautions by ensuring controlled access to premises to avoid drug diversion, including adequate legend drug storage, alarm system security, and adequate lighting and protection of the premises.

F. Finished products, warehouse control, and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and the lot or control number of the drug. Records shall be retained a minimum of two years after the distribution of the drug has been completed, or for one year after the expiration date of the drug, whichever is longer.

G. To assure the quality of the finished product, warehouse control shall include a system whereby the oldest approved stock is distributed first.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008).

§2741 Distribution

A. A distributor licensee handling controlled substances in Schedules I or II shall maintain complete and accurate records of the original copies of all order forms received and filled for orders of controlled substances within these schedules. This file shall be kept separate from the licensee's other business and professional records and shall be kept in this file a minimum of two years from the date the order was filled.

B. A distributor licensee handling controlled substances in Schedules III, IV, and V shall maintain complete and accurate records of all distributions for a minimum of two years from the date of each distribution. These records shall contain the full name, address, and registration number, if any, of the recipient, the common or established name of the controlled substance, its dosage, form, and strength, amount, and date of distribution.

C. A distributor shall not sell or distribute drugs or drug devices except to a person or facility authorized by law or regulation to procure or possess drugs or drug devices.

D. A distributor shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods.

E. A distributor shall maintain a written policy for handling recalls and withdrawals of products due to:

1. Any voluntary action on the part of the manufacturer;

2. The direction of the Food and Drug Administration, or any other federal, state, or local government agency; or
3. Replacement of existing merchandise with an approved product with a new package design.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008).

§2743 Procurement Requirements

A. Orders for Schedule I and II Controlled Substances

1. General Requirements

A licensee acquiring controlled substances in Schedules I and II shall maintain a file of the duplicate copies of all order forms used to obtain controlled substances within these schedules. Each duplicate copy of any order form used to order controlled substances shall be kept in this file a minimum of two years from the date the order form was completed. This file shall be kept separate from the licensee's other business or professional records. These records shall contain the full name, address and license number of the supplier, the common or established name of the controlled substance, its dosage form and strength, the amount, and the date of receipt.

2. DEA Form 222

Either a DEA Form 222 or its electronic equivalent is required for each distribution of a Schedule I or II controlled substance except for the following:

a. distributions to persons exempted from registration by federal or state law.
b. exports from the United States that conform to federal requirements.
c. deliveries to a registered analytical laboratory or its agent approved by DEA.
d. delivery from a central fill pharmacy to a retail pharmacy.

3. Electronic Orders

a. Electronic orders for Schedule I or II controlled substances shall comply with the federal requirements set forth in 21 CFR §1305.21 and §1311 or their successors.

i. To be valid, the purchaser shall sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided by federal law.

ii. The following data fields shall be included on an electronic order for Schedule I and II controlled substances:

(a) a unique number the purchaser assigns to track the order. The number shall be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.
(b) the purchaser's DEA registration number.
(c) the name of the supplier.
(d) the complete address of the supplier (may be completed by either the purchaser or the supplier).
(e) the supplier's DEA registration number (may be completed by either the purchaser or the supplier).
(f) the date the order is signed.
(g) the name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).
(h) the quantity in a single package or container.
(i) the number of packages or containers of each item ordered.

iii. An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.

b. Procedure for Filling Electronic Orders

i. A purchaser shall submit the order to a specific supplier. The supplier may initially process the order (*e.g.*, entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The licensee shall maintain control of the processing of the order at all times.

ii. A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under federal law.

iii. A supplier shall do the following before filling the order:

(a) Verify the integrity of the signature and the order by using software that complies with federal law to validate the order.
(b) Verify that the digital certificate has not expired.
(c) Check the validity of the certificate holder's certificate by checking the DEA's Certificate Revocation List.
(d) Verify the licensee's eligibility to order the controlled substances by checking the certificate extension data.

iv. The supplier shall retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record shall also include any data on the original order that the supplier completes. Software used to process digitally signed orders shall comply with DEA's requirements digital certificates for electronic orders.

v. If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser.

vi. A supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

vii. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and archived.

B. Orders for Schedule III, IV, and V Controlled Substances

All licensees acquiring controlled substances in Schedules III, IV, or V shall maintain complete and accurate records of all order forms a minimum of two years from the date of each such receipt. These records shall contain the full name, address, and license number of the supplier, the common or established name of the controlled substance, its dosage form and strength, the amount and the date of receipt.

C. Acquisition of Controlled Dangerous Substances by Institutional Facilities

1. A Louisiana-licensed pharmacy in possession of a valid Louisiana CDS license and DEA registration may include a portion of its controlled dangerous substance inventory within an emergency drug kit (EDK) placed in a non-federally registered institutional facility, but only under the following conditions:
   a. The EDK bears a valid EDK permit issued by the board; and
   b. The inclusion and management of controlled dangerous substances in such EDK shall comply with the provisions of Section 1713.J of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2148 (October 2008), amended LR 39:313 (February 2013).

§2745 Prescriptions

A. Practitioners Authorized to Issue Prescriptions

A prescription for a controlled substance may be issued only by an individual practitioner who is:

1. authorized by law to prescribe controlled substances, and includes the following:
   a. a physician,
   b. a dentist,
   c. a veterinarian,
   d. a physician assistant (but no substances listed in Schedule II, and only as permitted by supervising physician),
   e. an advanced practice registered nurse (but only as permitted by collaborating physician),
   f. an optometrist (but no substances listed in Schedule II), or
   g. a medical psychologist (but no narcotics);
2. in possession of a valid license from the appropriate state professional licensing agency, and is not restricted by that agency from prescribing controlled substances; and
3. in possession of a valid registration from the U.S. Drug Enforcement Administration (DEA), unless otherwise exempted from that registration requirement.

B. Purpose of Issue

1. A prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual

practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing of controlled substances rests upon the prescribing practitioner; however, a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act (21 USC 829), and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

2. A prescription shall not be issued or dispensed in order for an individual practitioner to obtain controlled substances for supplying the individual for the purpose of general dispensing or administration to patients.

3. A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the federal Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment and the prescribing practitioner is in compliance with the federal rules governing such activities.

C. Manner of Issuance

1. All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued.
2. All prescriptions for controlled substances shall contain the following information:
   a. full name and address of the patient;
   b. drug name, strength and dosage form;
   c. quantity of drug prescribed;
   d. directions for use; and
   e. name, address, telephone number and DEA registration number of the prescriber.
3. A prescription issued for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the DEA or a written notice stating that the practitioner is acting under the good faith exception of 21 CFR §1301.28(d).
4. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter, and they shall be manually signed by the prescriber.
   a. The prescriptions may be prepared by the secretary or agent for the signature of the prescriber, but the prescriber is responsible in case the prescription does not conform in all essential respects to the law and regulations.
   b. A corresponding liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed by DEA regulations or these rules.
5. A prescriber exempted from registration under 21 CFR §1301.22(c) shall include on all such prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution, in lieu of the registration number of the practitioner required by this Section. Each such written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.
6. An official exempted from registration under 21 CFR §1301.22(c) shall include on all prescriptions issued by him his branch of service or agency and his service identification number, in lieu of the registration number of the practitioner required by this Section. Each such prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.
7. Format Requirements. With the exception of medical orders written for patients in facilities licensed by the department, prescription forms shall adhere to the following requirements:
   a. Written Prescriptions.
      i. The prescription form shall not be smaller than four inches by five inches, provided however, that forms used by pharmacists to record telephoned or transferred prescriptions shall be exempt from this requirement.
      ii. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and DEA Registration Number. In the event multiple prescribers are identified on the prescription form, the prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling, the prescriber's printed name.
      iii. In the event the authorized prescriber is an advanced practice registered nurse or a physician's assistant, the prescription form shall clearly indicate the prescriber's practice affiliation. The affiliated physician's name, address, and telephone number shall appear on the prescription form.
      iv. The prescription form shall contain no more than four prescription drug or device orders. While nothing in these rules shall prohibit the pre-printing of any number of prescription drugs or devices on

the prescription form, no prescription form issued by a prescriber shall identify more than four prescription drugs or devices to be dispensed.

v. For each prescription drug or device ordered on a prescription form, there shall be a pre-printed check box labeled "Dispense as Written", or "DAW", or both.

vi. For each prescription drug or device ordered on a prescription form, there shall be a refill instruction, if any.

vii. The prescription form shall bear a single printed signature line, and the prescriber shall manually sign the prescription.

b. Oral Prescriptions.

i. With the exception of prescriptions for controlled substances listed in Schedule II, a prescription issued by a prescriber may be communicated to a pharmacist by an employee or agent of the prescriber.

ii. Upon the receipt of an oral prescription from a prescriber or his agent, the pharmacist shall reduce the order to a written form prior to dispensing the controlled substance.

iii. The pharmacist shall record all of the information identified in this Subsection on the prescription form.

D. Practitioners Authorized to Dispense Prescriptions.

1. A prescription for a controlled substance shall only be dispensed by a pharmacist, acting in the usual course of his professional practice, and either registered individually or employed in a registered pharmacy; however, nothing in this Section shall prohibit a physician, dentist, or veterinarian from personally dispensing such prescriptions to his own patients, in conformance with the laws and rules promulgated by the DEA and his own professional licensing agency.

2. Practitioners dispensing controlled substances shall procure and store those controlled substances in conformance with the requirements specified in this Chapter.

3. Practitioners dispensing controlled substances shall dispense only those controlled substances which they have acquired through the procurement and distribution procedures described in this Chapter; a practitioner shall not dispense any controlled substances possessed by another practitioner.

E. Administering Narcotic Drugs

1. A practitioner may administer or provide directly, but not prescribe, a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

a. the practitioner is separately registered with the DEA as a narcotic treatment program; and

b. the practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to federal law.

2. Nothing in this Subsection shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

3. This Subsection is not intended to impose any limitations on a physician or authorized hospital staff to administer or provide narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or provide directly narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

4. A practitioner may prescribe, administer or provide directly any narcotic drug listed in Schedule III, IV, or V approved by the FDA specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of 21 CFR §1301.28.

F. Controlled Substances Listed in Schedule II

1. Requirements of Prescription

a. A pharmacist may dispense a controlled substance listed in Schedule II only pursuant to a written prescription, except as provided in Subparagraph F.1.f of this Section.

b. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled

substance, except for the following three circumstances:

i. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.

ii. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.

iii. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile, provided that the practitioner or practitioner's agent has noted on the prescription that the patient is a hospice patient. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.

c. The original prescription shall be maintained in accordance with §2731.B.7 of this Chapter.

d. An individual practitioner may administer or provide directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to the provisions of Subsection E of this Section.

e. An institutional practitioner may administer or provide directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is provided for immediate administration to the ultimate user.

f. Authorization for Emergency Dispensing

An emergency situation exists when administration of the drug is necessary for immediate treatment, an appropriate alternate treatment is not available, and the prescribing practitioner cannot reasonably provide a written prescription. In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

i. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescriber);

ii. the prescription shall be immediately reduced to written form by the pharmacist and shall contain all information described in Paragraph C.2 of this Section, except for the signature of the prescriber;

iii. if the prescriber is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from a registered prescriber, which may include a callback to the prescriber using his telephone number as listed in the telephone directory or other good faith efforts to insure his identity; and

iv. within seven days after authorizing an emergency oral prescription, the prescriber shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Subsection C of this Section, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to written form. The pharmacist shall notify the nearest office of the DEA if the prescriber fails to deliver a written prescription to him within the required time; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescriber.

g. Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a pharmacist or an individual practitioner.

h. Notwithstanding the requirements of this Subsection, a prescription for a controlled substance listed in

Schedule II may be generated, signed, transmitted or received in electronic form, but not until permitted by the DEA, and then only in conformance with the rules established for such procedures.

2. Expiration Date of Prescriptions

A prescription for a controlled substance listed in Schedule II shall expire six months after the date of issue. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.

3. Refilling of Prescriptions; Issuance of Multiple Prescriptions

a. The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

b. An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a controlled substance listed in Schedule II, provided the following conditions are met:

i. each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice;

ii. the individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be dispensed immediately) indicating the earliest date on which a pharmacist may dispense each prescription;

iii. the individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

iv. the individual practitioner complies fully with all other applicable requirements under federal law and these rules.

G. Controlled Substances Listed in Schedules III, IV, and V

1. Requirements of Prescription

a. A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V which is a prescription drug only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy, or in the alternative, to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist containing all the information required in Subsection C of this Section, except for the signature of the prescriber.

b. An individual practitioner may administer or provide directly a controlled substance listed in Schedule III, IV, or V without a prescription, in the course of his professional practice, subject to the provisions of Subsection E of this Section.

c. An institutional practitioner may administer or provide directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist (containing all information required in Subsection C of this Section except for the signature of the prescriber), or pursuant to an order for medication made by an individual practitioner which dispensed for immediate administration to the ultimate user in conformance with the requirements of Subsection E of this Section.

d. A prescription issued by a prescriber may be communicated to a pharmacist by an employee or agent of the prescriber.

e. Notwithstanding the requirements of this Subsection, a prescription for a controlled substance listed in Schedule III, IV, or V may be generated, signed, transmitted or received in electronic form, but not until permitted by the DEA, and then only in conformance with the rules established for such procedures.

2. Expiration Date of Prescriptions

A prescription for a controlled substance listed in Schedule III, IV, or V shall expire six months after the date of issue, or following the acquisition of the number of refills authorized by the prescriber on the original prescription, whichever shall first occur. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.

3. Refilling of Prescriptions

The prescriber may authorize the refilling of a prescription for a controlled substance listed in Schedule III, IV, or V by including specific refill instructions on the prescription prior to its issuance. The maximum number of refills the prescriber may authorize is five (5). In the absence of a specific refill instruction on the original prescription from the prescriber, the prescription shall not be refilled.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008).

§2747 Dispensing Requirements

A. Location of Dispensing Activities

A pharmacist may dispense a prescription for a controlled substance pursuant to a valid prescription or order while in the usual course of his professional practice, but only within a prescription department in a pharmacy licensed by the board. A valid prescription or order is a prescription or order issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.

B. Prescriptions for Controlled Substances Listed in Schedule II

1. Oral Prescriptions

A pharmacist may accept and dispense an oral prescription from a prescribing practitioner, but only under the conditions described in, and in conformance with the requirements of, §2745.F.1.f of this Chapter.

2. Prescriptions Received by Facsimile Equipment

a. The facsimile equipment designated for the receipt of prescriptions shall be located within a prescription department in a pharmacy. The paper or other media used in the facsimile equipment designated for the receipt of prescriptions shall be non-fading and technically capable of providing a legible prescription.

b. A pharmacist shall not dispense a prescription based solely on a copy of the prescription received by facsimile, except under the circumstances described in §2745.F.1.b.i, ii, or iii.

c. In the event the facsimile transmission does not clearly identify the prescriber's office or other authorized location as the point of origin of the transmission, the pharmacist shall verify the authenticity of the prescription prior to dispensing the controlled substance.

3. Expiration Date

A pharmacist shall not dispense a prescription for a controlled substance listed in Schedule II more than six months after the date of issue of the prescription.

4. Completion of Prescription Form

In the event a pharmacist receives a prescription for a controlled substance listed in Schedule II lacking certain required information, the pharmacist may consult with the prescriber (but not the prescriber's agent) to clarify the prescriber's intent. Following a consultation with the prescriber and the appropriate documentation thereof on the prescription form:

a. A pharmacist may record changes to the following data elements on the prescription form:
   i. patient's address;
   ii. drug strength;
   iii. quantity prescribed; or
   iv. directions for use.

b. A pharmacist may add the following data elements on the prescription form:
   i. patient's address;
   ii. drug dosage form; or
   iii. prescriber's DEA registration number; however,

c. A pharmacist shall never make changes to or add the following data elements on the prescription form:
   i. patient's name;
   ii. date of issue;
   iii. drug name (except for generic interchange as permitted by law); or
   iv. prescriber signature.

5. Partial Filling of Prescription

a. The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written (or emergency oral) prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be dispensed within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescriber. No further quantity shall be dispensed beyond 72 hours without a new prescription.

b. A prescription for a controlled substance listed in Schedule II written for a patient in a long term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescriber prior to partially filling the prescription. Both the pharmacist and the prescriber have a responsibility to assure that the controlled substance is for a terminally ill patient.

i. The pharmacist shall record on the prescription form whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of these controlled substance rules.

ii. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

iii. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed.

iv. Notwithstanding the requirements of §2745.F.2, prescriptions for patients with a medical diagnosis documenting a terminal illness or for patients in a LTCF shall be valid for a period of time not to exceed 60 days from the date of issue unless terminated sooner by the discontinuance of the medication.

c. Information pertaining to current prescriptions for controlled substances listed in Schedule II for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

i. output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of the medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription, and the information required in §2747.A.5.b.

ii. immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

iii. retrieval of partially filled prescription information.

6. Refills

A pharmacist shall not refill a prescription for a controlled substance listed in Schedule II.

7. Labeling of Dispensed Medication and Filing of Prescription

a. The pharmacist dispensing a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a dispensing label containing the following data elements:

i. name, address and telephone number of the pharmacy;

ii. prescription number;

iii. date of dispensing;

iv. prescribing practitioner's name;

v. patient's name;

vi. drug name and strength;

vii. directions for use;

viii. pharmacist's name or initials;

ix. the following warning statement: "*Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed*", provided however, that this statement shall not be required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."

x. other cautionary or auxiliary labels as applicable.

b. If the prescription is dispensed at a central fill pharmacy, the pharmacist at the central fill pharmacy shall affix to the package a label showing the name and address of the retail pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, as well as the data elements itemized above in Subsection B.7.a.

c. The requirements of Subsection B.7.a shall not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, provided that:

i. no more than a seven (7) day supply of the medication is dispensed at one time;

ii. the medication is not in the possession of the ultimate user prior to the administration;

iii. the institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of controlled substances listed in Schedule II; and

iv. the system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

d. After dispensing a prescription for a controlled substance listed in Schedule II, the pharmacist shall cancel the prescription by defacing the prescription form and recording his name or initials on the form.

e. All written prescriptions and written records of emergency oral prescriptions shall be maintained in accordance with the requirements of §2731.B.7.

8. Provision of Prescription Information between Retail Pharmacies and Central Fill Pharmacies

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall apply:

a. Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile. The retail pharmacy transmitting the prescription information shall:

i. record the words "CENTRAL FILL" on the face of the original prescription and record the name, address and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

ii. ensure that all information required to be on a prescription pursuant to §2745.C is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

v. maintain the original prescription for a period of two years from the date the prescription was filled;

vi. keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

b. The central fill pharmacy receiving the transmitted prescription shall:

i. keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address and DEA registration number of the retail pharmacy transmitting the prescription;

ii. keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist dispensing the prescription, and the date of dispensing of the prescription;

iii. keep a record of the date the dispensed prescription was delivered to the retail pharmacy and the method of delivery (private, common or contract carrier).

C. Prescriptions for Controlled Substances Listed in Schedule III, IV, or V

1. Oral Prescriptions

Upon the receipt of an oral prescription from a prescriber or his agent, the pharmacist shall immediately reduce the prescription information to written form. The pharmacist may then dispense the prescription and file the written record in his prescription files.

2. Prescriptions Received by Facsimile Equipment

a. The facsimile equipment designated for the receipt of prescriptions shall be located within a prescription department in a pharmacy. The paper or other media used in the facsimile equipment designated for the receipt of prescriptions shall be non-fading and technically capable of providing a legible prescription.

b. The facsimile may serve as the original prescription form. After dispensing the prescription, the pharmacist shall file the facsimile prescription form in his prescription files.

c. In the event the facsimile transmission does not clearly identify the prescriber's office or other authorized location as the point of origin of the transmission, the pharmacist shall verify the authenticity of the prescription prior to dispensing the controlled substance.

3. Expiration Date

A pharmacist shall not dispense a prescription for a controlled substance listed in Schedule III, IV, or V more than six months after the date of issue. Further, when the number of refills authorized by the prescribing practitioner on the original prescription form have been dispensed, the prescription has expired; the pharmacist shall not dispense any further medication pursuant to that expired prescription.

4. Refilling of Prescriptions

a. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times.

b. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document shall be uniformly maintained and readily retrievable. The following information shall be retrievable by the prescription number: name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

c. As an alternative to the procedures described in Subparagraph C.4.b of this Section, an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III, IV, and V, subject to the following conditions:

i. Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

ii. Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

iii. Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance orders refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document. This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. The printout shall be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound logbook, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

iv. Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name, or both). Such a printout shall include the name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the prescription number. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours. If the board or an agent of the board requests a copy of such printout from the user pharmacy, the pharmacy shall verify the printout transmittal capability of its system by documentation, e.g., postmark.

v. In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which will be used for documentation of refills on prescriptions for controlled substances listed in Schedule III, IV, or V. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

5. Partial Filling of Prescriptions

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

a. the information (and the manner in which it is recorded) for a partial filling is the same as that required for a refill;

b. the number of partial fillings is not limited; however, the total quantity dispensed in all partial fillings shall not exceed the total quantity authorized on the original prescription. The total quantity authorized may be calculated as the sum of: (i) the quantity prescribed, and (ii) the calculated amount of the quantity prescribed times the number of refills originally authorized by the prescriber; and

c. no dispensing shall occur more than six months after the date on which the prescription was issued.

6. Labeling of Medications and Filing of Prescriptions

a. The pharmacist dispensing a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a dispensing label containing the following data elements:

i. name, address and telephone number of the pharmacy;
ii. prescription number;
iii. date of dispensing;
iv. prescribing practitioner's name;
v. patient's name;
vi. drug name and strength;
vii. directions for use;
viii. pharmacist's name or initials;
ix. for controlled substances listed in Schedules III or IV, the following warning statement: *"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"*, provided however, that this statement shall not be required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."
x. other cautionary or auxiliary labels as applicable.

b. If the prescription is dispensed at a central fill pharmacy, the pharmacist at the central fill pharmacy shall affix to the package a label showing the name and address of the retail pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, as well as the data elements itemized above in Subparagraph C.6.a of this Section.

c. The requirements of Subparagraph C.6.a of this Section shall not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized, provided that:

i. no more than a 34-day supply, or 100 dosage units, whichever is less, is dispensed at one time;
ii. the medication is not in the possession of the ultimate user prior to the administration;
iii. the institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of controlled substances listed in Schedule III, IV, and V; and
iv. the system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

d. After dispensing an original prescription for a controlled substance listed in Schedule III, IV, or V, the pharmacist shall record his name or initials on the form.

e. All prescription forms shall be maintained in accordance with the requirements of §2731.B.7.

7. Transfer between Pharmacies of Prescription Information for Schedule III, IV, or V for Refill Purposes

a. The transfer of prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements.

i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(a) invalidation of the prescription;
(b) on the reverse of the invalidated prescription, the name, address, and DEA registration number of the pharmacy to which it was transferred, and the name of the pharmacist receiving the prescription information; and
(c) the date of the transfer and the name of the pharmacist transferring the information.

ii. The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(a) indication of the transferred nature of the prescription;
(b) provide all information required for a prescription for a controlled substance (full name and address of the patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, telephone number, and DEA registration number of the prescribing practitioner) and include:

(i) date of issuance of original prescription;
(ii) original number of refills authorized on original prescription;
(iii) date of original dispensing;
(iv) number of valid refills remaining and date(s) and locations of previous refill(s);

(v) pharmacy's name, address, and DEA registration number and prescription number from which the prescription information was transferred;
(vi) name of pharmacist who transferred the prescription; and
(vii) pharmacy's name, address, and DEA registration number and prescription number from which the prescription was originally filled

iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.

iv. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

8. Provision of Prescription Information between Retail Pharmacies and Central Fill Pharmacies

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall apply:

a. Prescriptions for controlled substances listed in Schedule III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile. The retail pharmacy transmitting the prescription information shall:

i. record the words "CENTRAL FILL" on the face of the original prescription and record the name, address and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

ii. ensure that all information required to on a prescription pursuant to §2745.C is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

iii. indicate in the information transmittal the number of refills already dispensed and the number of refills remaining;

iv. maintain the original prescription for a period of two years from the date the prescription was last refilled; and

v. keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

b. The central fill pharmacy receiving the transmitted prescription shall:

i. keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address and DEA registration number of the retail pharmacy transmitting the prescription;

ii. keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist dispensing the prescription, and the dates of filling or refilling of the prescription;

iii. keep a record of the date the dispensed prescription was delivered to the retail pharmacy and the method of delivery (private, common or contract carrier).

D. Dispensing Controlled Substances without a Prescription

A controlled substance listed in Schedule II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. such dispensing is made only by a pharmacist, and not by a non-pharmacist employee even if under the supervision of a pharmacist – although after the pharmacist has fulfilled his professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist;
2. not more than 240 milliliters, or 8 ounces, of any such controlled substance containing opium, nor more than 120 milliliters, or 4 ounces, of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
3. the purchaser is at least 18 years of age;
4. the pharmacist requires every purchaser of a controlled substance under this Paragraph not known to him to furnish suitable identification (including proof of age where appropriate);
5. a bound record book for dispensing of controlled substances under this Paragraph is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the controlled substance to the purchaser; further, this book shall be maintained in conformance with the recordkeeping requirements identified in §2731.B.7;
6. a prescription is not required for dispensing of the controlled substance pursuant to any federal or state law;

7. central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this Paragraph.

E. Professional Conduct

A license, registration, certification, permit, or any other credential deemed necessary to practice, or assist in the practice of, pharmacy may be subject to discipline when deviating from primary or corresponding responsibility to avert the following prohibited acts:

1. Primary Responsibility.
   a. drug diversion – attempted, actual or conspired dispensing, distributing, administering, or manufacturing of a controlled substance not pursuant to a valid prescription or order while acting in the course of professional pharmacy practice is prohibited; or
   b. possession – actual or conspired possession of a controlled substance not pursuant to a valid prescription or order issued for a legitimate medical purpose by an authorized practitioner in the usual course of professional practice.
2. Corresponding Responsibility.
   a. Medical Purpose. The prescribing practitioner has the primary responsibility to issue a prescription for a controlled substance for a legitimate medical purpose, but a corresponding responsibility rests with the pharmacist or dispensing physician dispensing said prescription to ascertain that said prescription was issued for a legitimate medical purpose in the usual course of professional practice.
   b. Authenticity. A pharmacist or dispensing physician shall exercise sound professional judgment to ascertain the validity of prescriptions for controlled substances. If, in the pharmacist's professional judgment, a prescription is not valid, said prescription shall not be dispensed.
3. Forged Prescriptions. It is unlawful to forge a prescription, or to dispense a forged prescription, for a controlled substance. The pharmacist or dispensing physician shall exercise professional diligence in determining the validity of a prescription as to the practitioner's authority and/or patient's identity, in order to prevent misrepresentation, fraud, deception, subterfuge, conspiracy, or diversion of controlled substances.
4. Altered Prescriptions. It is unlawful to personally alter a prescription, or to dispense an altered prescription, for a controlled substance, except as provided by §2747.B.4 of this Chapter.

F. Accountability

The pharmacist-in-charge, the owner of a pharmacy permit, and/or other designated responsible parties, shall be accountable for shortages of controlled substances or inconsistencies indicated in an audit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008).

§2749 Disposal of Controlled Substances

A. Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the DEA in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

1. if the person is a licensee, he shall list the controlled substance or substances which he desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his area; or
2. if the person is not a licensee, he shall submit to the Special Agent in Charge a letter stating:
   a. the name and address of the person;
   b. the name and quantity of each controlled substance to be disposed of;
   c. how the applicant obtained the substance, if known; and
   d. the name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

B. The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

1. by transfer to person licensed by the board and authorized to possess the substance;
2. by delivery to an agent of the DEA or to the nearest office of the DEA;
3. by destruction in the presence of an agent of the DEA or other authorized person; or
4. by such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

C. In the event that a licensee is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the licensee to dispose of such substances, in accordance with this Section, without prior approval of the DEA in each instance, on the condition that the licensee keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the licensee. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008).

§2751 Distributions and Transfers of Controlled Substances

A. Distribution by Dispenser to Another Practitioner or Reverse Distributor

1. A dispenser may distribute (without being registered to distribute) a quantity of such controlled substance to:
   a. another practitioner for the purpose of general dispensing by the practitioner to patients, provided that:
      i. the receiving practitioner is authorized to dispense that controlled substance;
      ii. the distribution is recorded by the dispenser and the receiving practitioner, in accordance with §2735.B of this Chapter;
      iii. a DEA 222 order form is used as required for controlled substances listed in Schedule II; and
      iv. the total number of dosage units of all controlled substances distributed by the dispenser pursuant to this Section during each calendar year shall not exceed 5 percent of the total number of dosage units distributed and dispensed by the dispenser during the same calendar year.
   b. a reverse distributor who is authorized to receive such controlled substances.
2. If, during any calendar year the dispenser has reason to believe the total number of dosage units of all controlled substances which will be distributed by him pursuant to this Section will exceed 5 percent of his total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the dispenser shall obtain a license to distribute controlled substances.
3. The distributions made by a retail pharmacy to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations shall not count toward the 5 percent limit described in this Section.

B. Distribution to Supplier or Manufacturer

1. Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the controlled substance, or if designated, to the manufacturer's registered agent or accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the controlled substance, the name, address, and DEA Registration Number, if any, of the person making the distribution, and the name, address, and DEA Registration Number of the supplier or manufacturer. In the case of returning a controlled substance listed in Schedule I or II, a DEA 222 order form shall be used and maintained as the written record of the transaction. Any person not required to register shall be exempt from maintaining the records required by this Section.
2. Distributions referred to in this Subsection may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned, provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008).

Subchapter G. Administrative Procedures

§2753 Inspections

The board may inspect any licensed facility or location of a licensed person including pertinent records for the purpose of determining compliance with the requirements of this Chapter and other state and federal laws and regulations related to controlled substances, subject to the limitations identified in R.S. 40:988.B and R.S. 40:988.C.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).

§2755 Seizures

The board may place under seal all drugs or devices that are owned by or in the possession, custody, or control of a licensee at the time his license is suspended or revoked, for a licensee's failure to timely renew his license, or at the time the board refuses to renew his license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).

§2757 Hearings

All formal administrative hearings conducted by the board shall be conducted in accordance with the Louisiana Administrative Procedures Act, La. R.S. 49:950, *et seq.*, and §2711 of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII – Pharmacists

Chapter 29. Prescription Monitoring Program

Subchapter A. General Operations

§2901. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them unless the context clearly indicates otherwise:

Administer or *Administration* – the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

Advisory Council – the entity established in R.S. 40:1005.

Board – the Louisiana Board of Pharmacy.

Controlled Substance – any substance or drug defined, enumerated, or included in federal or state statute or rules, 21 CFR 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. *Controlled Substance* shall not include distilled spirits, wine, malt beverages, or tobacco.

Dispense or *Dispensing* – the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

Dispenser – a person authorized by this state to dispense or distribute to the ultimate user any controlled substance or drug monitored by the program, but shall not include any of the following:

a. a pharmacy permitted by the board as a hospital pharmacy that dispenses or distributes any controlled substance or drug monitored by the program for the purposes of inpatient health care;

b. a practitioner who dispenses or distributes no more than a single forty-eight hour supply of such controlled substance or drug to a patient prior to, or subsequent to, performing an actual procedure on that patient;

c. a practitioner or other authorized person who administers such controlled substance or drug upon the lawful order of a practitioner;

d. a wholesale distributor of such controlled substance or drug that is credentialed by the Louisiana State Board of Wholesale Drug Distributors;

e. a veterinarian who dispenses negligible amounts of controlled substances or drugs of concern, as identified by rule

Distribute or *Distribution* – the delivery of a drug or device other than by administering or dispensing.

Drug – any of the following:

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 disease in humans or animals;

b. any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

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 – drugs other than controlled substances as defined by rule which demonstrate a potential for abuse, including any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, esters, ethers, isomers, and salts of isomers [whenever the existence of such salts, esters, ethers, isomers, and salts of isomers is possible within the specific chemical designation]:

a. butalbital when in combination with at least 325 milligrams of acetaminophen per dosage unit; and

b. tramadol.

Patient – the person or animal who is the ultimate user of a controlled substance or drug monitored by the program for whom a prescription is issued and for whom a controlled substance or drug is dispensed.

Prescriber – a licensed health care professional with prescriptive authority.

Prescription Monitoring Information – data submitted to and maintained by the prescription monitoring program.

Prescription Monitoring Program or *PMP* – the program established in R.S. 40:1004.

Procedure – any dental or medical practice or process described in the current year's version of the American Dental Association's *Current Dental Terminology* or the American Medical Association's *Code of Procedural Terminology*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1345 (July 2007), amended LR 36:755 (April 2010), effective September 1, 2010, amended LR 39:314 (February 2013).

§2903. Authority for Program Operation

A. The board shall establish and maintain, in consultation with and upon the recommendation of the advisory council, an electronic system for the monitoring of controlled substances and drugs of concern dispensed in the state or dispensed to an address in the state.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1004.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1345 (July 2007).

§2905. Authority to Engage Staff

A. The board shall have the authority to engage a program director and sufficient number of other personnel as may be necessary to accomplish the mission of the program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1179.F.(6).
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007).

§2907. Authority to Contract with Vendors

A. The board shall have the authority to engage vendors to facilitate the collection of the prescription monitoring program data and to facilitate access to the program data by authorized users.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1012.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007).

§2909. Advisory Council

A. The advisory council shall consist of the following members, each of whom may appoint a designee:
   1. the president of the Louisiana State Board of Medical Examiners;
   2. the president of the Louisiana State Board of Dentistry;
   3. the president of the Louisiana State Board of Nursing;
   4. the president of the Louisiana State Board of Optometry Examiners;
   5. the president of the Louisiana State Board of Veterinary Medicine;
   6. the president of the Louisiana Academy of Physician Assistants;
   7. the president of the Louisiana Board of Pharmacy;
   8. the superintendent of the Louisiana State Police;
   9. the administrator of the United States Drug Enforcement Administration;
   10. the speaker of the Louisiana House of Representatives;
   11. the president of the Louisiana Senate;
   12. the chairman of the House Committee on Health and Welfare;
   13. the chairman of the Senate Committee on Health and Welfare;
   14. the secretary of the Department of Health and Hospitals;
   15. the president of the Louisiana State Medical Society;
   16. the president of the Louisiana Dental Association;
   17. the president of the Louisiana Association of Nurse Practitioners;
   18. the president of the Optometry Association of Louisiana;
   19. the president of the Louisiana Pharmacists Association;

20. the president of the Louisiana Independent Pharmacies Association;
21. the president of the National Association of Chain Drug Stores;
22. the president of the Louisiana Sheriffs' Association;
23. the president of the Louisiana District Attorneys Association;
24. the president of the Pharmaceutical Research and Manufacturers of America;
25. the president of the Louisiana Academy of Medical Psychologists;
26. the president of the Louisiana Veterinary Medical Association

B. The members of the advisory council shall serve at the pleasure of their respective appointing authorities, eleven of whom shall constitute a quorum for the transaction of business. The members shall elect a chairman and vice chairman whose duties shall be established by the advisory council. The board shall fix a time and place for regular meetings of the advisory council, which shall meet at least quarterly. The advisory council shall establish policies and procedures necessary to carry out its duties.

C. The board shall seek, and the advisory council shall provide, information and advice regarding the development and operation of the electronic monitoring system, including but not limited to the following:
1. which controlled substances should be monitored;
2. which drugs of concern demonstrate a potential for abuse and should be monitored;
3. design and implementation of educational courses identified in R.S. 40:1008;
4. the methodology to be used for analysis and interpretation of prescription monitoring information;
5. design and implementation of a program evaluation component;
6. identification of potential additional members to the advisory council.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1005.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013).

Subchapter B. Data Collection

§2911. Reporting of Prescription Monitoring Information

A. Each dispenser shall submit to the board information regarding each prescription dispensed for a controlled substance.

B. Each dispenser shall submit the required information by electronic means as soon as possible but in no event more than seven days after the date of dispensing.

C. If the dispenser is unable to submit prescription information by electronic means, he may apply to the board for a waiver. The board may grant a waiver to that requirement; if so, the waiver shall state the format and frequency with which the dispenser shall submit the required information. The waiver shall expire one year after the date of issue, unless terminated sooner by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013).

§2913. Required Data Elements

A. The information submitted for each prescription shall include data relative to the identification of the following elements of the transaction, or alternative data as identified in the board's program user manual. To the extent possible, the data shall be transmitted in the format established by the American Society for Automation in Pharmacy (ASAP) Telecommunications Format for Prescription Monitoring Programs Standard Version 4.2 or a successor.
1. Prescriber Information;
   a. last and first name of prescriber;
   b. United States Drug Enforcement Administration (DEA) registration number, and suffix if applicable, or in the alternative, the national provider identifier (NPI) number, as issued by the United States Centers for Medicare and Medicaid Services (CMS).
2. Patient Information;
   a. last and first name of human patient and middle initial or name if available, or in the event of a veterinary prescription, the client's name and patient's animal species;

b. complete address of patient;
c. date of birth of patient;
d. identification number of patient;
e. gender code;
f. species code.

3. Prescription Information;
   a. identification number of prescription;
   b. date of issuance;
   c. date of fulfillment;
   d. number of refills authorized on original prescription and refill number;
   e. method of payment for prescription (cash, insurance, or government subsidy).
4. Drug Information;
   a. National Drug Code (NDC) number;
   b. quantity dispensed;
   c. days supply.
5. Dispenser Information;
   a. DEA registration number, or in the alternative, the national provider identifier (NPI) number.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013).

§2915. Failure to Report Prescription Information

A. A dispenser who fails to submit prescription monitoring information to the board as required shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007).

Subchapter C. Access to Prescription Monitoring Information

§2917. Authorized Direct Access Users of Prescription Monitoring Information

A. The following persons may access prescription monitoring information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:
   1. persons authorized to prescribe or dispense controlled substances or drugs of concern, for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescription records;
   2. designated representatives from the professional licensing, certification, or regulatory agencies of this state or another state charged with administrative oversight of those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern;
   3. designated representatives from the Louisiana Medicaid program regarding Medicaid program recipients;
   4. designated representatives of the board or any vendor or contractor establishing or maintaining the prescription monitoring program;
   5. prescription monitoring programs located in other states, through a secure interstate data exchange system or health information exchange system approved by the board, but only in compliance with the provisions of R.S. 40:1007(G).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013).

§2919. Registration Procedures for Authorized Direct Access Users

A. Authorized users of prescription monitoring information shall comply with the following requirements

to register with the board, in order to receive the appropriate credentials to access prescription monitoring information.

1. The applicant shall successfully complete the program's orientation course, and attach evidence of same to his application to the program.
2. The applicant shall file an application with the program, using the form supplied by the program for that purpose.
3. The board shall verify the practitioner applicant is in possession of a valid license to prescribe or dispense controlled substances, or in the case of an agency applicant, the board shall verify agency representation.
4. Upon verification of all requirements, the board shall issue the appropriate credential necessary to access prescription monitoring information.
5. Upon receipt of information that an authorized user no longer possesses authority to prescribe or dispense controlled substances, the program shall terminate the user's credentials to access prescription monitoring information. If or when the user's authority to prescribe or dispense controlled substances is reinstated, the program may reinstate the user's credentials to access prescription monitoring information.

AUTHORITY NOTE: Promulgated by R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007).

§2921. Methods of Access to Prescription Monitoring Information

A. Prescribers and dispensers, once properly registered, may solicit prescription monitoring information from the program concerning their patients, or for verifying their prescription records. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

B. Designated representatives from agencies charged with administrative oversight of prescribers and dispensers of controlled substances may solicit prescription monitoring information from the program concerning specific investigations of prescribers or dispensers. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

C. Designated representatives of the Louisiana Medicaid program, once properly registered, may solicit prescription monitoring information from the program concerning specific recipients. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.

D. Designated representatives of the board, or any vendor or contractor establishing or maintaining the program, once properly registered, may solicit prescription monitoring information from the program for the purpose of establishing or maintaining the program's database.

E. Upon receipt of one of the following methods of application by local, state, out-of-state, or federal law enforcement or prosecutorial officials, the program may provide prescription monitoring information:
   1. a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
   2. a grand jury subpoena; or
   3. an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided by law enforcement to the board, and further, provided all of the following:
      a. the information sought is relevant and material to a legitimate law enforcement inquiry;
      b. the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought;
      c. de-identified information, or limited information that does not identify or could not reasonably lead to the identification of an individual patient, could not reasonably be used.

F. Individuals may solicit their own prescription monitoring information from the program. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.

G. Program personnel, once properly registered, may solicit prescription monitoring information from the program's database for the purpose of responding to legitimate inquiries from authorized users or other individuals.

H. Prescription monitoring programs located in other states may access prescription monitoring information from the program through a secure interstate data exchange system or health information exchange system approved by the board,

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013).

§2923. Unlawful Use or Disclosure of Prescription Monitoring Information

A. If the program receives evidence of inappropriate or unlawful use or disclosure of prescription monitoring information by an authorized user, the program shall refer that user to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).

Subchapter D. Reports

§2925. Release of Prescription Monitoring Information to Other Entities

A. The program shall provide prescription monitoring information to public or private entities, whether located in or outside of the state, for public research, policy, or educational purposes, but only after removing information that identifies or could reasonably be used to identify prescribers, dispensers, and individual patients or persons who received prescriptions from prescribers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR 39:315 (February 2013).

§2927. Legislative Oversight

A. The board shall report to the appropriate legislative oversight committee on a periodic basis, but in no case less than annually, the cost benefits and other information relevant to policy, research, and education involving controlled substances and other drugs of concern monitored by the program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).

§2929. Program Evaluation

A. The board shall, in consultation with and upon recommendation of the advisory council, design and implement an evaluation component to identify cost benefits of the prescription monitoring program and other information relevant to policy, research, and education involving controlled substances and drug monitored by the prescription monitoring program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).

Subchapter E. Exemptions

§2931. Exemptions

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR 39:315 (February 2013).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 31. Illegal Payments; Required Disclosures of Financial Interests

Subchapter A. General Information

§3101. Scope and Purpose of Chapter

A. Scope of Chapter. The rules of this chapter interpret, implement, and provide for the enforcement of R.S. 37:1744 and R.S. 37:1745, or their successors, requiring disclosure of a pharmacist's financial interest in another health care provider to whom or to which the pharmacist refers a patient and prohibiting certain payments in return for referring or soliciting patients.

B. Declaration of Purpose; Interpretation and Application. Pharmacists owe a fiduciary duty to patients to exercise their professional judgment in the best interests of their patients in providing, furnishing, recommending, or referring patients for health care items or services. The purpose of these rules and the laws they implement is to prevent payments by or to a pharmacist as a financial incentive for the referral of patients to a pharmacist or other health care provider for healthcare services or items. These rules shall be interpreted, construed, and applied so as to give effect to such purposes and intent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004, repromulgated LR 34:2158 (October 2008).

§3103. Definitions

A. As used in this Chapter, the following terms have the meaning ascribed to them by this section:

Board – the Louisiana Board of Pharmacy.

Financial Interest – a significant ownership or investment interest established through debt, equity, or other means and held, directly or indirectly, by a pharmacist or a member of a pharmacist's immediate family, or any form of direct or indirect remuneration for referral.

Group Practice – a group of two or more pharmacists and/or other health care providers legally organized as a general partnership, registered limited liability partnership, professional medical corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar organization or association:

a. in which each pharmacist who is a member of the group provides substantially the full range of services which the pharmacist routinely provides;

b. for which substantially all of the services of the pharmacists who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group;

c. in which no pharmacist who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the pharmacist, except payment of a share of the overall profits of the group, which may include a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share of profits or bonus is not determined in any manner which is directly related to the volume or value of referrals by such pharmacist; and

d. in the case of a faculty practice plan associated with a hospital, institution of higher education, or pharmacy school with an approved training program in which pharmacist members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, solely with respect to services provided within such faculty practice plan.

Health Care Item – any substance, product, device, equipment, supplies, or other tangible good or article which is or may be used or useful in the provision of health care.

Health Care Provider – any person, partnership, corporation, or association licensed by a department, board, commission, or other agency of the state of Louisiana to provide, or which does in fact provide preventive, diagnostic, or therapeutic health care services or items.
Immediate Family – as respects a pharmacist, the pharmacist's spouse, children, parents, siblings, stepchildren, stepparents, in-laws, grandchildren, and grandparents.
Investment Interest – a security issued by an entity, including, without limitation, shares in a corporation, interests in or units of a partnership or limited liability company, bonds, debentures, notes, or other debt instruments.
Payment – transfer or provision of money, goods, services, or anything of economic value.
Person – as defined in R.S. 37:1164(33). or its successor.
Pharmacist – any individual currently licensed by the board to engage in the practice of pharmacy in the state of Louisiana.
Pharmacy – any place where drugs are dispensed and pharmacy primary care is provided.
Referral – any direction, recommendation, or suggestion given by a health care provider to a patient, directly or indirectly, which is likely to determine, control, or influence the patient's choice of another health care provider for the provision of health care services or items.
Remuneration for Referral – any arrangement or scheme, involving any remuneration, directly or indirectly, in cash or in kind, between a pharmacist, or an immediate family member of such pharmacist, and another health care provider that is intended to induce referrals by the pharmacist to the health care provider or by the health care provider to the pharmacist, other than any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the furnishing of any health care item or service.
Significant Financial Interest – an ownership or investment interest shall be considered "significant", within the meaning of §3113, if such interest satisfies any of the following tests:

a. Such interest, in dollar amount or value, represents five percent or more of the ownership or investment interests of the health care provider in which such interest is held; or
b. Such interest represents five percent or more of the voting securities of the health care provider in which such interest is held.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004, repromulgated LR 34:2158 (October 2008).

Subchapter B. Illegal Payments

§3105. Prohibition of Payments for Referrals

A. A pharmacist or pharmacy shall not knowingly and willfully make, or offer to make, any payment, directly or indirectly, overtly or covertly, in cash or in kind, to induce another person to refer an individual to the pharmacist for the furnishing, or arranging for the furnishing, of any health care item or service.
B. A pharmacist or pharmacy shall not knowingly and willfully solicit, receive, or accept any payment, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a health care provider for the furnishing, or arranging for the furnishing, of any health care item or service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2159 (October 2008).

§3107. Prohibited Arrangements

A. Any arrangement or scheme, including cross-referral arrangements, which a pharmacist or pharmacy knows or should know has a principal purpose of ensuring or inducing referrals by the pharmacist to another health care provider, which, if made directly by the pharmacist or pharmacy would be a violation of §3113, shall constitute a violation of §3113.

AUTHORITY NOTE: Promulgated in accordance with R.S. 38:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2159 (October 2008).

§3109. Exceptions

A. Proportionate Return on Investment. Payments or distributions by an entity representing a direct return on investment based upon a percentage of ownership, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or §3105 of these regulations.

B. General Exceptions. Any payment, remuneration, practice, or arrangement which is not prohibited by or unlawful under §1128(b) of the Federal Social Security Act (Act), 42 U.S.C. §1320a-7b(b), or its successor, with respect to health care items or services for which payment may be made under Title XVIII or Title XIX of the Act, including those payments and practices sanctioned by the secretary of the United States Department of Health and Human Services, through the Office of the Inspector General, pursuant to §1128B(b)(3)(E) of the Act, through regulations promulgated at 42 CFR §1001.952, or its successor, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or by §3105 of these rules with respect to health care items or services for which payment may be made by any patient or private or governmental payor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated 34:2159 (October 2008).

§3111. Effect of Violation

A. Any violation of, or failure of compliance with, the prohibitions and provision of §3105 of this chapter shall be deemed a violation of the Pharmacy Practice Act, R.S. 37:1161 et seq, providing cause for the board to sanction a person culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

Subchapter C. Disclosure of Financial Interests in Third-Party Health Care Providers

§3113. Required Disclosure of Financial Interest

A. Mandatory Disclosure. A pharmacist or pharmacy shall not make any referral of a patient outside the pharmacist's or pharmacy's group practice for the provision of health care items or services by another health care provider in which the referring pharmacist has a financial interest, unless, in advance of any such referral, the referring pharmacist or pharmacy discloses to the patient, in accordance with §3113 of this chapter, the existence and nature of such financial interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 17:780 (August 1991), amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

§3115. Form of Disclosure

A. Required Contents. The disclosure required by §3113 of this chapter shall be made in writing, shall be furnished to the patient, or the patient's authorized representative, prior to or at the time of making the referral, and shall include:

1. the pharmacist's or pharmacy's name, address, and telephone number;
2. the name and address of the health care provider to whom the patient is being referred by the pharmacist or pharmacy;

3. the nature of the items or services which the patient is to receive from the health care provider to which the patient is being referred; and
4. the existence and nature of the pharmacist's or pharmacy's financial interest in the health care provider to which the patient is being referred.

B. Permissible Contents. The form of disclosure required by §3113 of this chapter may include a signed acknowledgment by the patient or the patient's authorized representative that the required disclosure has been given.

C. Approved Form. Notice to a patient given substantially in the form of Disclosure of Financial Interest prescribed in the Appendix to this rule shall be presumptively deemed to satisfy the disclosure requirements of this subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

§3117. Effect of Violation; Sanctions

A. Effect of Violation. Any violation of, or failure of compliance with, the prohibitions and provision of §3113 of this chapter shall be deemed a violation of the Pharmacy Practice Act, R.S. 37:1161 et seq., providing cause for the board to sanction a pharmacist or pharmacy culpable of such violation.

B. Administrative Sanctions. In addition to the sanctions provided for by R.S. 37:1241, upon proof of violation of §3113 by a pharmacist or pharmacy, the board may order that all or any portion of any amounts paid by a patient, and/or by any third-party payor on behalf of a patient, for health care items or services furnished upon a referral by the pharmacist or pharmacy in violation of §3113, be refunded by the pharmacist or pharmacy to such patient and/or third-party payor, together with legal interest on such payments at the rate prescribed by law calculated from the date on which any such payment was made by the patient and/or third-party payors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004, repromulgated 34:2160 (October 2008).

§3119. Disclosure of Financial Interest

[Name of Pharmacist/Group]
[Address]
[Telephone Number]

DISCLOSURE OF FINANCIAL INTEREST
As Required by R.S. 37:1744 and LAC 46:LIII.3113-3115

TO: _____ DATE: _____

_____
(Name of Patient to Be Referred)

_____
(Patient Address)

Louisiana law requires pharmacists and other health care providers to make certain disclosures to a patient when they refer a patient to another health care provider or facility in which the pharmacist has a significant financial interest. [I am/we are] referring you, or the named patient for whom you are legal representative, to:

_____
(Name and Address of Provider to Whom Patient is Referred)

to obtain the following health care services, products, or items:

_____
(Purpose of the Referral)

[I/we] have a financial interest in the health care provider to whom we are referring you, the nature and extent of which are as follows:

_____

_____

PATIENT ACKNOWLEDGEMENT

I, the above-named patient, or legal representative of such patient, hereby acknowledge receipt, on the date indicated and prior to the described referral, of a copy of the foregoing Disclosure of Financial Interest.

_____
Signature of Patient or Patient's Representative)

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004, repromulgated 34:2160 (October 2008).

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 33. Severability

§3301. Severability

A. In the event any rule, sentence, clause, or phrase or any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof, and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Louisiana Board of Pharmacy to establish rules and regulations that are constitutional and enforceable so as to safeguard the health, safety, and welfare of the people of the State.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2114 (October 2003), effective January 1, 2004, repromulgated LR 33:1348 (July 2007).