REGULATORY PROJECT 2026-01 - CONTROLLED DANGEROUS SUBSTANCES

DRAFT #3 (CODED VERSION)

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. - Pharmacists

Chapter 27. Controlled Dangerous Substances

Subchapter A. General Provisions

§2701. Definitions

A. ~~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:~~ As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise; any term not defined herein shall have the definition set forth in R.S. 40:961, or, if not defined there, the common usage and meaning as stated in the Merriam-Webster's Collegiate Dictionary, Eleventh Edition (as revised), or other similarly accepted reference texts:

~~*Administer* or A*dministration* - 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.

CFR—Code of Federal Regulations

~~*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.

~~*Dispense* or *Dispensing*—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*—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 Board of Drug and Device Distributors to engage in the distribution of drugs or devices, including controlled substances.~~

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 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.

Hemp Facility—a facility licensed by the Louisiana Department of Agriculture and Forestry as a hemp seed producer, hemp grower, hemp handler or hemp processor.

~~*Hospital*—a facility licensed by the department to operate as a hospital.~~

LDAF—Louisiana Department of Agriculture and Forestry, or its successor.

License—a Louisiana Controlled Dangerous Substances (CDS) License.

Licensee—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).

~~*Reverse Distribute*—to acquire controlled substances from another registrant or law enforcement for the purpose of:~~

~~a. return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or~~

~~b. destruction.~~

~~*Reverse Distributor*—is a person registered by the DEA as a reverse distributor.~~

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.

~~*Supplier*—any person registered by the DEA who is entitled to fill order forms for controlled substances.~~

Third-Party Logistics Provider—a person who provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate or intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

~~*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), amended by the Department of Health, Board of Pharmacy, LR 46:569 (April 2020), amended LR 46:793 (June 2020), LR 47:1640 (November 2021), LR 48:494 (March 2022), amended LR

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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.~~

A. Each CDS licensee shall comply with all applicable provisions of 21 CFR Parts 1300-1399.

B. Records and Reports

1. All records required under 21 CFR Parts 1300-1399 shall be made available to the board, or its authorized agents, for inspection and copying upon request.

2. Reports submitted to the Automation of Reports and Consolidated Orders System (ARCOS) shall be provided to the board upon request.

C. Theft or Significant Loss

1. A licensee shall notify the board in writing of any theft or significant loss of controlled substances, in accordance with 21 CFR Part 1301.

D. Prescription Expiration

1. A prescription for a Schedule II controlled substance shall expire 90 days after the date it is issued.

2. A prescription for a Schedule III or IV controlled substance shall expire six months after the date it is issued or upon completion of the authorized refills specified by the prescriber, whichever occurs first.

3. A prescription for a Schedule V controlled substance shall expire one year after the date it is issued or upon completion of the authorized refills specified by the prescriber, whichever occurs first.

E. Exception to Inventory Requirements of 21 CFR 1304.11

1. Pharmacies shall conduct an annual inventory of all controlled substances on hand. This inventory may be taken on any date, provided it is no later than 385 days after the previous inventory.

2. Pharmacies shall also conduct a new inventory under the following circumstances:

a. upon the designation of a new pharmacist-in-charge;

b. upon discovery of any theft or significant loss of controlled substances;

c. upon the departure of a pharmacist-in-charge; and

d. upon the permanent closure of the pharmacy.

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), amended LR

§2715. Physical Security Controls for Non-Practitioners, Narcotic Treatment Programs, and Compounders for Narcotic Treatment Programs - Repealed

~~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 1/2 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 1 inch in diameter;

(b). set in concrete or installed with lag bolts which are pinned or brazed; and

(c). placed no more than 10 feet apart with horizontal 1 1/2 inch reinforcements every 60 inches;

ii. having a mesh construction with openings of not more than 2 1/2 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), repealed LR

§2717. Physical Security Controls for Practitioners and Pharmacies - Repealed

~~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), repealed LR

§2719. Security Controls for Freight Forwarding Facilities - Repealed

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), repealed LR

§2721. Employee Screening by Non-Practitioners - Repealed

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), repealed LR

Subchapter D. Labeling and Packaging Requirements

§2723. Symbol Required - Repealed

~~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 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~~

~~1. 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), repealed LR

§2725. Location and Size of Symbol on Label and Labeling - Repealed

~~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), repealed LR

§2727. Sealing of Controlled Substances - Repealed

~~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), repealed LR

§2729. Labeling and Packaging Requirements for Imported and Exported Controlled Substances - Repealed

~~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), repealed LR

Subchapter E. Recordkeeping Requirements

§2731. General Information - Repealed

~~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, third-party logistics provider, 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), amended by the Department of Health, Board of Pharmacy, LR 46:570 (April 2020), repealed LR

§2733. Inventory Requirements - Repealed

~~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, Third Party Logistics Providers, Dispensers, Researchers, Importers, Exporters, and Chemical Analysts. Each person registered or authorized to manufacture, distribute, dispense, import, export, provide logistics services, 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 and Third Party Logistics Providers. 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), amended by the Department of Health, Board of Pharmacy, LR 46:570 (April 2020), repealed LR

§2735. Continuing Records - Repealed

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, Third-Party Logistics Providers, 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 and Third-Party Logistics Providers. Each person authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section.

3. Record for Dispensers and Researchers

a. 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.

b. 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.

c. In addition to the requirements of this Paragraph, practitioners dispensing gamma hydroxybutyric acid under a prescription shall also comply with federal law.

d. Pharmacies dispensing prescriptions for controlled substances shall use a dispensing information system capable of accurately recording partial fills and refills.

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, 30 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.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2142 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020), amended LR 49:681 (April 2023), repealed LR

§2737. Reports - Repealed

~~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 fifteenth 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.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2145 (October 2008), repealed LR

Subchapter F. Production, Distribution, and Utilization

§2739. Manufacture - Repealed

~~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), repealed LR

§2741. Distribution - Repealed

~~A. A distributor or third-party logistics provider 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 or third-party logistics provider 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 or third-party logistics provider 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 or third-party logistics provider shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods.~~

~~E. A distributor or third-party logistics provider 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), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020), repealed LR

§2743. Procurement Requirements - Repealed

~~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), repealed LR

§2745. Prescriptions - Repealed

~~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;~~

~~e. an advanced practice registered nurse;~~

~~f. an optometrist; 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. 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.

4. 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 hand printed on it, as well as the signature of the physician.

5. An official exempted from registration under 21 CFR §1301.23 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 hand printed on it, as well as the signature of the officer.

6. 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 4 inches by 5 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. 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.

iv. 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.

v. For each prescription drug or device ordered on a prescription form, there shall be a refill instruction, if any.

vi. 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.

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 call back 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 90 days 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. A prescription for a controlled substance listed in Schedule III or IV 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.~~

~~b. A prescription for a controlled substance listed in Schedule V shall expire one year 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.~~

~~c. No pharmacist shall dispense any controlled substances pursuant to an expired prescription.~~

~~3. Refilling of Prescriptions~~

~~a. The prescriber may authorize the refilling of a prescription for a controlled substance listed in Schedule III or IV by including specific refill instructions on the prescription prior to its issuance. The maximum number of refills the prescriber may authorize is five.~~

~~b. The prescriber may authorize the refilling of a prescription for a controlled substance listed in Schedule V by including specific refill instructions on the prescription prior to its issuance. There is no limitation on the number of refills the prescriber may authorize, subject however to the one year expiration date of the prescription.~~

~~c. In the absence of specific refill instructions on the original prescription from the prescriber, the prescription shall not be refilled.~~

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016), amended LR 47:1645 (November 2021), amended LR 49:1556 (September 2023), repealed LR

§2747. Dispensing Requirements - Repealed

~~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 90 days 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 with the following limitations:

i. When the pharmacist is unable to supply the full quantity called for in a written (or emergency oral) prescription, he shall make 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.

ii. When a partial fill is requested by the patient or the prescriber, the pharmacist shall dispense a quantity less than the total quantity prescribed. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. No remaining portion of a partial filling may be dispensed more than 30 days after the date on which the prescription was written. The requirement for a pharmacist to comply with a patient or prescriber request to dispense a partial fill shall not supersede the pharmacist’s obligation relative to corresponding responsibility as described in Subsection E of this Section.

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-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);

iii. maintain the original prescription for a period of two years from the date the prescription was filled;

iv. 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. A prescription for a controlled substance listed in Schedule III or IV 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.

b. A prescription for a controlled substance listed in Schedule V shall expire one year 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.

c. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.

4. Refilling of Prescriptions

a. No prescription for a controlled substance listed in Schedule III or IV 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. No prescription for a controlled substance listed in Schedule V shall be filled or refilled more than one year after the date on which such prescription was issued.

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. When requested by the patient or prescriber, the pharmacist shall dispense a partial fill of a controlled substance listed in Schedules III, IV or V, provided that:~~

~~a. the information required for a partial filling, and the manner in which it is recorded, 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;~~

~~c. no dispensing shall occur more than six months after the date on which the prescription for a controlled substance listed in Schedule III or IV was issued, or more than one year after the date on which the prescription for a controlled substance listed in Schedule V was issued; and~~

~~d. the requirement for a pharmacist to comply with a patient or prescriber request to dispense a partial fill shall not supersede the pharmacist's obligation relative to corresponding responsibility as described in Subsection E of this Section.~~

~~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 Paragraph 2731.B.7 of this Chapter.

7. The transfer between pharmacies of a prescription or prescription information for controlled substances is permissible in conformance with 21 CFR Part 1306.

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 be on a prescription pursuant to Subsection 2745.C of this Chapter 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;

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 the book shall be maintained in conformance with the recordkeeping requirements identified in Paragraph 2731.B.7 of this Chapter;

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.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 46:577 (April 2020), LR 47:1645 (November 2021), amended LR 49:681 (April 2023), amended LR 50:1827 (December 2024), repealed LR

§2749. Disposal of Controlled Substances - Repealed

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.

D. When a patient or his designee wishes to return previously dispensed controlled dangerous substances to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:

1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.

2. The pharmacy shall comply with the provisions of 21 CFR §1317 or its successor for the pharmacy's disposal 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 34:2157 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:794 (June 2020), repealed LR

§2751. Distributions and Transfers of Controlled Substances - Repealed

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, Third-Party Logistics Provider, 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), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020) repealed LR

Subchapter G. Administrative Procedures

§2753. Inspections - Repealed

~~A. 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), repealed LR

§2755. Seizures - Repealed

~~A. 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), repealed LR

§2757. Hearings - Repealed

~~A. All formal administrative hearings conducted by the board shall be conducted in accordance with the Louisiana Administrative Procedures Act, 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) repealed LR