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).

§2737. Reports

A. Reports from Manufacturers Importing Narcotic Raw Material

1. Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted in compliance with 21 CFR §1304.31or its successor.
2. The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):
    a. beginning inventory;
    b. gains on reweighing;
    c. imports;
    d. other receipts;
    e. quantity put into process;
    f. losses on reweighing;
    g. other dispositions; and
    h. ending inventory.
3. The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):
    a. beginning inventory;
    b. gains on reweighing;
    c. quantity extracted from narcotic raw material;
    d. quantity produced/manufactured/synthesized;
    e. quantity sold;
    f. quantity returned to conversion processes for reworking;
    g. quantity used for conversion;
    h. quantity placed in process;
    i. other dispositions;
    j. losses on reweighing; and
    k. ending inventory.
4. The following information shall be submitted for importation of each narcotic raw material:
    a. import permit number;
    b. date shipment arrived at the United States port of entry;
    c. actual quantity shipped;
    d. assay (percent) of morphine, codeine and thebaine; and
    e. quantity shipped, expressed as anhydrous morphine alkaloid.
5. Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer

in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

6. Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.
7. All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it shall no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

B. Reports from Manufacturers Importing Coca Leaves

1. Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted in compliance with 21 CFR §1304.32.
2. The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):
   a. beginning inventory;
   b. imports;
   c. gains on reweighing;
   d. quantity purchased;
   e. quantity produced;
   f. other receipts;
   g. quantity returned to processes for reworking;
   h. material used in purification for sale;
   i. material used for manufacture or production;
   j. losses on reweighing;
   k. material used for conversion;
   l. other dispositions; and
   m. ending inventory.
3. The following information shall be submitted for importation of coca leaves:
   a. import permit number;
   b. date the shipment arrived at the United States port of entry;
   c. actual quantity shipped;
   d. assay (percent) of cocaine alkaloid; and
   e. total cocaine alkaloid content.
4. Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.
5. Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.
6. All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it shall no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

C. Reports to ARCOS

1. Reports generally. All reports required by this Subsection shall be filed with the ARCOS Unit, PO 28293,

Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit. A copy of the report shall be filed with the board.

2. Frequency of Reports. Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a licensee may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that licensee. Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing. These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a licensee may be given permission to file more frequently (but not more frequently than quarterly).
3. Persons Reporting. For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III and gamma- hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in Paragraph 4 of this Subsection.
4. Substances Covered.
    a. Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:
        i. Schedule III
            (a) benzphetamine;
            (b) cyclobarbital;
            (c) methyprylon; and
            (d) phendimetrazine.
        ii. Schedule IV
            (a) barbital;
            (b) diethylpropion (amfepramone);
            (c) ethchlorvynol;
            (d) ethinamate;
            (e) lefetamine (SPA);
            (f) mazindol;
            (g) meprobamate;
            (h) methylphenobarbital;
            (i) phenobarbital;
            (j) phentermine; and
            (k) pipradrol.
    b. Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.
5. Transactions reported. Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.
6. Exceptions. A registered institutional practitioner who repackages or relabels exclusively for distribution or

who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the licensee may be exempted from filing reports under this section by applying to the ARCOS Unit of the DEA.

D. Reports of Theft or Loss
The licensee shall notify the New Orleans Field Division Office of the DEA, or its successor, and the board, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of such theft or loss. The supplier is responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Subsection E of this Section, within one business day of discovery of such theft or loss. The licensee shall also complete, and submit to the New Orleans Field Division Office of the DEA, or its successor, and the board, DEA Form 106, or its electronic equivalent, regarding the theft or loss. Thefts and significant losses shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a licensee should consider, among others, the following factors:
1. the actual quantity of controlled substances lost in relation to the type of business;
2. the specific controlled substances lost;
3. whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. whether the specific controlled substances are likely candidates for diversion; and
6. local trends and other indicators of the diversion potential of the missing controlled substance.

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).

Subchapter F. Production, Distribution and Utilization

§2739. Manufacture

A. A licensee located in Louisiana engaged in the manufacture of controlled dangerous substances within Schedules I, II, III, IV, or V shall prepare a complete and accurate record of the date of manufacture, the theoretical and actual yields, the quantity used for quality control, the identity of batch numbers or other appropriate identification, and the quantity of any product reworked for any reason for each manufactured batch of controlled dangerous substances or each manufactured batch of drugs in which a controlled dangerous substance was used as a raw material.

B. The licensee shall maintain manufacturing records in such a manner that the identity of a batch of controlled dangerous substances finished product can be matched to the identity of the controlled dangerous substance raw material used to make that product.

C. The licensee shall maintain any other such records as are necessary to account for all controlled dangerous substances used in the manufacturing process.

D. A building where manufacturing takes place shall be maintained in a clean and orderly manner and shall be of a suitable size, construction, and location to facilitate cleaning, maintenance, processing, and packing, labeling, or storing of legend drugs pursuant to federal and state requirements.

E. All manufacturers shall employ security precautions by ensuring controlled access to premises to avoid drug diversion, including adequate legend drug storage, alarm system security, and adequate lighting and protection of the premises.

F. Finished products, warehouse control, and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and the lot or control

number of the drug. Records shall be retained a minimum of two years after the distribution of the drug has been completed, or for one year after the expiration date of the drug, whichever is longer.

G. To assure the quality of the finished product, warehouse control shall include a system whereby the oldest approved stock is distributed first.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008).

§2741. Distribution

A. A distributor licensee handling controlled substances in Schedules I or II shall maintain complete and accurate records of the original copies of all order forms received and filled for orders of controlled substances within these schedules. This file shall be kept separate from the licensee's other business and professional records and shall be kept in this file a minimum of two years from the date the order was filled.

B. A distributor licensee handling controlled substances in Schedules III, IV, and V shall maintain complete and accurate records of all distributions for a minimum of two years from the date of each distribution. These records shall contain the full name, address, and registration number, if any, of the recipient, the common or established name of the controlled substance, its dosage, form, and strength, amount, and date of distribution.

C. A distributor shall not sell or distribute drugs or drug devices except to a person or facility authorized by law or regulation to procure or possess drugs or drug devices.

D. A distributor shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods.

E. A distributor shall maintain a written policy for handling recalls and withdrawals of products due to:
   1. Any voluntary action on the part of the manufacturer;
   2. The direction of the Food and Drug Administration, or any other federal, state, or local government agency; or
   3. Replacement of existing merchandise with an approved product with a new package design.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008).

§2743. Procurement Requirements

A. Orders for Schedule I and II Controlled Substances
   1. General Requirements
      A licensee acquiring controlled substances in Schedules I and II shall maintain a file of the duplicate copies of all order forms used to obtain controlled substances within these schedules. Each duplicate copy of any order form used to order controlled substances shall be kept in this file a minimum of two years from the date the order form was completed. This file shall be kept separate from the licensee's other business or professional records. These records shall contain the full name, address and license number of the supplier, the common or established name of the controlled substance, its dosage form and strength, the amount, and the date of receipt.
   2. DEA Form 222
      Either a DEA Form 222 or its electronic equivalent is required for each distribution of a Schedule I or II controlled substance except for the following:
      a. distributions to persons exempted from registration by federal or state law.
      b. exports from the United States that conform to federal requirements.
      c. deliveries to a registered analytical laboratory or its agent approved by DEA.
      d. delivery from a central fill pharmacy to a retail pharmacy.
   3. Electronic Orders
      a. Electronic orders for Schedule I or II controlled substances shall comply with the federal requirements set forth in 21 CFR §1305.21 and §1311 or their successors.
         i. To be valid, the purchaser shall sign an electronic order for a Schedule I or II controlled substance

with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided by federal law.

ii. The following data fields shall be included on an electronic order for Schedule I and II controlled substances:
   (a) a unique number the purchaser assigns to track the order. The number shall be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.
   (b) the purchaser's DEA registration number.
   (c) the name of the supplier.
   (d) the complete address of the supplier (may be completed by either the purchaser or the supplier).
   (e) the supplier's DEA registration number (may be completed by either the purchaser or the supplier).
   (f) the date the order is signed.
   (g) the name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).
   (h) the quantity in a single package or container.
   (i) the number of packages or containers of each item ordered.

iii. An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.

b. Procedure for Filling Electronic Orders

i. A purchaser shall submit the order to a specific supplier. The supplier may initially process the order (*e.g.*, entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The licensee shall maintain control of the processing of the order at all times.

ii. A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under federal law.

iii. A supplier shall do the following before filling the order:
   (a) Verify the integrity of the signature and the order by using software that complies with federal law to validate the order.
   (b) Verify that the digital certificate has not expired.
   (c) Check the validity of the certificate holder's certificate by checking the DEA's Certificate Revocation List.
   (d) Verify the licensee's eligibility to order the controlled substances by checking the certificate extension data.

iv. The supplier shall retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record shall also include any data on the original order that the supplier completes. Software used to process digitally signed orders shall comply with DEA's requirements digital certificates for electronic orders.

v. If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser.

vi. A supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

vii. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and archived.

B. Orders for Schedule III, IV, and V Controlled Substances

All licensees acquiring controlled substances in Schedules III, IV, or V shall maintain complete and accurate records of all order forms a minimum of two years from the date of each such receipt. These records shall contain the full name, address, and license number of the supplier, the common or established name of the controlled substance, its dosage form and strength, the amount and the date of receipt.

C. Acquisition of Controlled Dangerous Substances by Institutional Facilities
   1. A Louisiana-licensed pharmacy in possession of a valid Louisiana CDS license and DEA registration may include a portion of its controlled dangerous substance inventory within an emergency drug kit (EDK) placed in a non-federally registered institutional facility, but only under the following conditions:
      a. The EDK bears a valid EDK permit issued by the board; and
      b. The inclusion and management of controlled dangerous substances in such EDK shall comply with the provisions of Section 1713.J of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2148 (October 2008), amended LR 39:313 (February 2013).

§2745. Prescriptions

A. Practitioners Authorized to Issue Prescriptions

A prescription for a controlled substance may be issued only by an individual practitioner who is:

1. authorized by law to prescribe controlled substances, and includes the following:
   a. a physician;
   b. a dentist;
   c. a veterinarian;
   d. a physician assistant;
   e. an advanced practice registered nurse;
   f. an optometrist;
   g. a medical psychologist (but no narcotics);
2. in possession of a valid license from the appropriate state professional licensing agency, and is not restricted by that agency from prescribing controlled substances; and
3. in possession of a valid registration from the U.S. Drug Enforcement Administration (DEA), unless otherwise exempted from that registration requirement.

B. Purpose of Issue

1. A prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing of controlled substances rests upon the prescribing practitioner; however, a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act (21 USC 829), and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
2. A prescription shall not be issued or dispensed in order for an individual practitioner to obtain controlled substances for supplying the individual for the purpose of general dispensing or administration to patients.
3. A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the federal Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment and the prescribing practitioner is in compliance with the federal rules governing such activities.

C. Manner of Issuance

1. All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued.
2. All prescriptions for controlled substances shall contain the following information:
   a. full name and address of the patient;
   b. drug name, strength and dosage form;
   c. quantity of drug prescribed;
   d. directions for use; and
   e. name, address, telephone number and DEA registration number of the prescriber.
3. A prescription issued for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the DEA or a written notice stating that the practitioner is acting under the good faith exception of 21 CFR §1301.28(d).
4. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter, and they shall be manually signed by the prescriber.

a. The prescriptions may be prepared by the secretary or agent for the signature of the prescriber, but the prescriber is responsible in case the prescription does not conform in all essential respects to the law and regulations.
b. A corresponding liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed by DEA regulations or these rules.

5. A prescriber exempted from registration under 21 CFR §1301.22(c) shall include on all such prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution, in lieu of the registration number of the practitioner required by this Section. Each such written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.
6. An official exempted from registration under 21 CFR §1301.22(c) shall include on all prescriptions issued by him his branch of service or agency and his service identification number, in lieu of the registration number of the practitioner required by this Section. Each such prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.
7. Format Requirements. With the exception of medical orders written for patients in facilities licensed by the department, prescription forms shall adhere to the following requirements:
   a. Written Prescriptions.
      i. The prescription form shall not be smaller than four inches by five inches, provided however, that forms used by pharmacists to record telephoned or transferred prescriptions shall be exempt from this requirement.
      ii. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and DEA Registration Number. In the event multiple prescribers are identified on the prescription form, the prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling, the prescriber's printed name.
      iii. 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 §1301.28.

F. Controlled Substances Listed in Schedule II

1. Requirements of Prescription
   a. A pharmacist may dispense a controlled substance listed in Schedule II only pursuant to a written prescription, except as provided in Subparagraph F.1.f of this Section.
   b. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except for the following three circumstances:
      i. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.
      ii. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.
      iii. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile, provided that the practitioner or practitioner's agent has noted on the prescription that the patient is a hospice patient. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.
   c. The original prescription shall be maintained in accordance with §2731.B.7 of this Chapter.
   d. An individual practitioner may administer or provide directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to the provisions of Subsection E of this Section.
   e. An institutional practitioner may administer or provide directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is provided for immediate administration to the ultimate user.
   f. Authorization for Emergency Dispensing

      An emergency situation exists when administration of the drug is necessary for immediate treatment, an appropriate alternate treatment is not available, and the prescribing practitioner cannot reasonably provide a written prescription. In the case of an emergency situation, a pharmacist may dispense a

controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

i. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescriber);

ii. the prescription shall be immediately reduced to written form by the pharmacist and shall contain all information described in Paragraph C.2 of this Section, except for the signature of the prescriber;

iii. if the prescriber is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from a registered prescriber, which may include a callback to the prescriber using his telephone number as listed in the telephone directory or other good faith efforts to insure his identity; and

iv. within seven days after authorizing an emergency oral prescription, the prescriber shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Subsection C of this Section, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to written form. The pharmacist shall notify the nearest office of the DEA if the prescriber fails to deliver a written prescription to him within the required time; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescriber.

g. Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a pharmacist or an individual practitioner.

h. Notwithstanding the requirements of this Subsection, a prescription for a controlled substance listed in Schedule II may be generated, signed, transmitted or received in electronic form, but not until permitted by the DEA, and then only in conformance with the rules established for such procedures.

2. Expiration Date of Prescriptions

A prescription for a controlled substance listed in Schedule II shall expire 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 prescription for a controlled substance listed in Schedule III, IV, or V shall expire six months after the date of issue, or following the acquisition of the number of refills authorized by the prescriber on the original prescription, whichever shall first occur. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.
3. Refilling of Prescriptions
   The prescriber may authorize the refilling of a prescription for a controlled substance listed in Schedule III, IV, or V by including specific refill instructions on the prescription prior to its issuance. The maximum number of refills the prescriber may authorize is five (5). In the absence of a specific refill instruction on the original prescription from the prescriber, the prescription shall not be refilled.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016).

§2747. Dispensing Requirements

A. Location of Dispensing Activities
   A pharmacist may dispense a prescription for a controlled substance pursuant to a valid prescription or order while in the usual course of his professional practice, but only within a prescription department in a pharmacy licensed by the board. A valid prescription or order is a prescription or order issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.

B. Prescriptions for Controlled Substances Listed in Schedule II
   1. Oral Prescriptions
      A pharmacist may accept and dispense an oral prescription from a prescribing practitioner, but only under the conditions described in, and in conformance with the requirements of, §2745.F.1.f of this Chapter.
   2. Prescriptions Received by Facsimile Equipment
      a. The facsimile equipment designated for the receipt of prescriptions shall be located within a prescription department in a pharmacy. The paper or other media used in the facsimile equipment designated for the receipt of prescriptions shall be non-fading and technically capable of providing a legible prescription.
      b. A pharmacist shall not dispense a prescription based solely on a copy of the prescription received by facsimile, except under the circumstances described in §2745.F.1.b.i, ii, or iii.
      c. In the event the facsimile transmission does not clearly identify the prescriber's office or other authorized location as the point of origin of the transmission, the pharmacist shall verify the authenticity of the prescription prior to dispensing the controlled substance.
   3. Expiration Date
      A pharmacist shall not dispense a prescription for a controlled substance listed in Schedule II more than 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, if the pharmacist is unable to supply the full quantity called for in a written (or emergency oral) prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be dispensed within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescriber. No further quantity shall be dispensed beyond 72 hours without a new prescription.
   b. A prescription for a controlled substance listed in Schedule II written for a patient in a long term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescriber prior to partially filling the prescription. Both the pharmacist and the prescriber have a responsibility to assure that the controlled substance is for a terminally ill patient.
      i. The pharmacist shall record on the prescription form whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of these controlled substance rules.
      ii. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.
      i. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed.
      ii. Notwithstanding the requirements of §2745.F.2, prescriptions for patients with a medical diagnosis documenting a terminal illness or for patients in a LTCF shall be valid for a period of time not to exceed 60 days from the date of issue unless terminated sooner by the discontinuance of the medication.
   c. Information pertaining to current prescriptions for controlled substances listed in Schedule II for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:
      i. output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of the medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription, and the information required in §2747.A.5.b.
      ii. immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
      iii. retrieval of partially filled prescription information.

6. Refills
   A pharmacist shall not refill a prescription for a controlled substance listed in Schedule II.

7. Labeling of Dispensed Medication and Filing of Prescription
    a. The pharmacist dispensing a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a dispensing label containing the following data elements:
        i. name, address and telephone number of the pharmacy;
        ii. prescription number;
        iii. date of dispensing;
        iv. prescribing practitioner's name;
        v. patient's name;
        vi. drug name and strength;
        vii. directions for use;
        viii. pharmacist's name or initials;
        ix. the following warning statement: "*Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"*, provided however, that this statement shall not be required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."
        x. other cautionary or auxiliary labels as applicable.
    b. If the prescription is dispensed at a central fill pharmacy, the pharmacist at the central fill pharmacy shall affix to the package a label showing the name and address of the retail pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, as well as the data elements itemized above in Subsection B.7.a.
    c. The requirements of Subsection B.7.a shall not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, provided that:
        i. no more than a seven (7) day supply of the medication is dispensed at one time;
        ii. the medication is not in the possession of the ultimate user prior to the administration;
        iii. the institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of controlled substances listed in Schedule II; and
        iv. the system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
    d. After dispensing a prescription for a controlled substance listed in Schedule II, the pharmacist shall cancel the prescription by defacing the prescription form and recording his name or initials on the form.
    e. All written prescriptions and written records of emergency oral prescriptions shall be maintained in accordance with the requirements of §2731.B.7.
8. Provision of Prescription Information between Retail Pharmacies and Central Fill Pharmacies
Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall apply:
    a. Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile. The retail pharmacy transmitting the prescription information shall:
        i. record the words "CENTRAL FILL" on the face of the original prescription and record the name, address and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
        ii. ensure that all information required to be on a prescription pursuant to §2745.C is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
        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 pharmacist shall not dispense a prescription for a controlled substance listed in Schedule III, IV, or V more than six months after the date of issue. Further, when the number of refills authorized by the prescribing practitioner on the original prescription form have been dispensed, the prescription has expired; the pharmacist shall not dispense any further medication pursuant to that expired prescription.

4. Refilling of Prescriptions

a. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times.

b. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document shall be uniformly maintained and readily retrievable. The following information shall be retrievable by the prescription number: name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

c. As an alternative to the procedures described in Subparagraph C.4.b of this Section, an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III, IV, and V, subject to the following conditions:

i. Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

ii. Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

iii. Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance orders refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document. This document shall be maintained in a separate file at that pharmacy for a

period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. The printout shall be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound logbook, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

iv. Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name, or both). Such a printout shall include the name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the prescription number. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours. If the board or an agent of the board requests a copy of such printout from the user pharmacy, the pharmacy shall verify the printout transmittal capability of its system by documentation, e.g., postmark.

v. In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which will be used for documentation of refills on prescriptions for controlled substances listed in Schedule III, IV, or V. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

5. Partial Filling of Prescriptions

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

a. the information (and the manner in which it is recorded) for a partial filling is the same as that required for a refill;

b. the number of partial fillings is not limited; however, the total quantity dispensed in all partial fillings shall not exceed the total quantity authorized on the original prescription. The total quantity authorized may be calculated as the sum of:

(i) the quantity prescribed, and

(ii) the calculated amount of the quantity prescribed times the number of refills originally authorized by the prescriber; and

c. no dispensing shall occur more than six months after the date on which the prescription was issued.

6. Labeling of Medications and Filing of Prescriptions

a. The pharmacist dispensing a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a dispensing label containing the following data elements:

i. name, address and telephone number of the pharmacy;

ii. prescription number;

iii. date of dispensing;

iv. prescribing practitioner's name;

v. patient's name;

vi. drug name and strength;

vii. directions for use;

viii. pharmacist's name or initials;

ix. for controlled substances listed in Schedules III or IV, the following warning statement: *"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"*, provided however, that this statement shall not be required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."

x. other cautionary or auxiliary labels as applicable.

b. If the prescription is dispensed at a central fill pharmacy, the pharmacist at the central fill pharmacy shall affix to the package a label showing the name and address of the retail pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating the prescription was

filled at the central fill pharmacy, as well as the data elements itemized above in Subparagraph C.6.a of this Section.

c. The requirements of Subparagraph C.6.a of this Section shall not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized, provided that:
   i. no more than a 34-day supply, or 100 dosage units, whichever is less, is dispensed at one time;
   ii. the medication is not in the possession of the ultimate user prior to the administration;
   iii. the institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of controlled substances listed in Schedule III, IV, and V; and
   iv. the system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

d. After dispensing an original prescription for a controlled substance listed in Schedule III, IV, or V, the pharmacist shall record his name or initials on the form.

e. All prescription forms shall be maintained in accordance with the requirements of §2731.B.7.

7. Transfer between Pharmacies of Prescription Information for Schedule III, IV, or V for Refill Purposes
   a. The transfer of prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements.
      i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
         (a) invalidation of the prescription;
         (b) on the reverse of the invalidated prescription, the name, address, and DEA registration number of the pharmacy to which it was transferred, and the name of the pharmacist receiving the prescription information; and
         (c) the date of the transfer and the name of the pharmacist transferring the information.
      ii. The pharmacist receiving the transferred prescription information shall reduce to writing the following:
         (a) indication of the transferred nature of the prescription;
         (b) provide all information required for a prescription for a controlled substance (full name and address of the patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, telephone number, and DEA registration number of the prescribing practitioner) and include:
            (i) date of issuance of original prescription;
            (ii) original number of refills authorized on original prescription;
            (iii) date of original dispensing;
            (iv) number of valid refills remaining and date(s) and locations of previous refill(s);
            (v) pharmacy's name, address, and DEA registration number and prescription number from which the prescription information was transferred;
            (vi) name of pharmacist who transferred the prescription; and
            (vii) pharmacy's name, address, and DEA registration number and prescription number from which the prescription was originally filled
      iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
      iv. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

8. Provision of Prescription Information between Retail Pharmacies and Central Fill Pharmacies
   Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall apply:
   a. Prescriptions for controlled substances listed in Schedule III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile. The retail pharmacy transmitting the prescription information shall:
      i. record the words "CENTRAL FILL" on the face of the original prescription and record the name, address and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

ii. ensure that all information required to on a prescription pursuant to §2745.C is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
iii. indicate in the information transmittal the number of refills already dispensed and the number of refills remaining;
iv. maintain the original prescription for a period of two years from the date the prescription was last refilled; and
v. keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

b. The central fill pharmacy receiving the transmitted prescription shall:
i. keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address and DEA registration number of the retail pharmacy transmitting the prescription;
ii. keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist dispensing the prescription, and the dates of filling or refilling of the prescription;
iii. keep a record of the date the dispensed prescription was delivered to the retail pharmacy and the method of delivery (private, common or contract carrier).

D. Dispensing Controlled Substances without a Prescription

A controlled substance listed in Schedule II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. such dispensing is made only by a pharmacist, and not by a non-pharmacist employee even if under the supervision of a pharmacist – although after the pharmacist has fulfilled his professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist;
2. not more than 240 milliliters, or 8 ounces, of any such controlled substance containing opium, nor more than 120 milliliters, or 4 ounces, of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
3. the purchaser is at least 18 years of age;
4. the pharmacist requires every purchaser of a controlled substance under this Paragraph not known to him to furnish suitable identification (including proof of age where appropriate);
5. a bound record book for dispensing of controlled substances under this Paragraph is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the controlled substance to the purchaser; further, this book shall be maintained in conformance with the recordkeeping requirements identified in §2731.B.7;
6. a prescription is not required for dispensing of the controlled substance pursuant to any federal or state law;
7. central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this Paragraph.

E. Professional Conduct

A license, registration, certification, permit, or any other credential deemed necessary to practice, or assist in the practice of, pharmacy may be subject to discipline when deviating from primary or corresponding responsibility to avert the following prohibited acts:

1. Primary Responsibility.
   a. drug diversion – attempted, actual or conspired dispensing, distributing, administering, or manufacturing of a controlled substance not pursuant to a valid prescription or order while acting in the course of professional pharmacy practice is prohibited; or
   b. possession – actual or conspired possession of a controlled substance not pursuant to a valid prescription or order issued for a legitimate medical purpose by an authorized practitioner in the usual course of professional practice.
2. Corresponding Responsibility.
   a. Medical Purpose. The prescribing practitioner has the primary responsibility to issue a prescription for a controlled substance for a legitimate medical purpose, but a corresponding responsibility rests with the pharmacist or dispensing physician dispensing said prescription to ascertain that said prescription was issued for a legitimate medical purpose in the usual course of professional practice.

b. Authenticity. A pharmacist or dispensing physician shall exercise sound professional judgment to ascertain the validity of prescriptions for controlled substances. If, in the pharmacist's professional judgment, a prescription is not valid, said prescription shall not be dispensed.

3. Forged Prescriptions. It is unlawful to forge a prescription, or to dispense a forged prescription, for a controlled substance. The pharmacist or dispensing physician shall exercise professional diligence in determining the validity of a prescription as to the practitioner's authority and/or patient's identity, in order to prevent misrepresentation, fraud, deception, subterfuge, conspiracy, or diversion of controlled substances.
4. Altered Prescriptions. It is unlawful to personally alter a prescription, or to dispense an altered prescription, for a controlled substance, except as provided by §2747.B.4 of this Chapter.

F. Accountability

The pharmacist-in-charge, the owner of a pharmacy permit, and/or other designated responsible parties, shall be accountable for shortages of controlled substances or inconsistencies indicated in an audit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008), amended LR 41:685 (April 2015).

§2749. Disposal of Controlled Substances

A. Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the DEA in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:
   1. if the person is a licensee, he shall list the controlled substance or substances which he desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his area; or
   2. if the person is not a licensee, he shall submit to the Special Agent in Charge a letter stating:
      a. the name and address of the person;
      b. the name and quantity of each controlled substance to be disposed of;
      c. how the applicant obtained the substance, if known; and
      d. the name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

B. The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:
   1. by transfer to person licensed by the board and authorized to possess the substance;
   2. by delivery to an agent of the DEA or to the nearest office of the DEA;
   3. by destruction in the presence of an agent of the DEA or other authorized person; or
   4. by such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

C. In the event that a licensee is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the licensee to dispose of such substances, in accordance with this Section, without prior approval of the DEA in each instance, on the condition that the licensee keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the licensee. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008).

§2751. Distributions and Transfers of Controlled Substances

A. Distribution by Dispenser to Another Practitioner or Reverse Distributor
   1. A dispenser may distribute (without being registered to distribute) a quantity of such controlled substance to:
      a. another practitioner for the purpose of general dispensing by the practitioner to patients, provided that:
         i. the receiving practitioner is authorized to dispense that controlled substance;
         ii. the distribution is recorded by the dispenser and the receiving practitioner, in accordance with

§2735.B of this Chapter;

iii. a DEA 222 order form is used as required for controlled substances listed in Schedule II; and

iv. the total number of dosage units of all controlled substances distributed by the dispenser pursuant to this Section during each calendar year shall not exceed 5 percent of the total number of dosage units distributed and dispensed by the dispenser during the same calendar year.

b. a reverse distributor who is authorized to receive such controlled substances.

2. If, during any calendar year the dispenser has reason to believe the total number of dosage units of all controlled substances which will be distributed by him pursuant to this Section will exceed 5 percent of his total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the dispenser shall obtain a license to distribute controlled substances.

3. The distributions made by a retail pharmacy to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations shall not count toward the 5 percent limit described in this Section.

B. Distribution to Supplier or Manufacturer

1. Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the controlled substance, or if designated, to the manufacturer's registered agent or accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the controlled substance, the name, address, and DEA Registration Number, if any, of the person making the distribution, and the name, address, and DEA Registration Number of the supplier or manufacturer. In the case of returning a controlled substance listed in Schedule I or II, a DEA 222 order form shall be used and maintained as the written record of the transaction. Any person not required to register shall be exempt from maintaining the records required by this Section.

2. Distributions referred to in this Subsection may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned, provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008).

Subchapter G. Administrative Procedures

§2753. Inspections

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).

§2755. Seizures

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).

§2757. Hearings

A. All formal administrative hearings conducted by the board shall be conducted in accordance with the Louisiana Administrative Procedures Act, La. R.S. 49:950, *et seq.*, and §2711 of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).