Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 1. Introduction

§109. Standing Board Committees

A. – B. …

C. ~~Reciprocity~~ Application Review Committee. ~~The reciprocity committee, consisting of at least three board members appointed at the discretion of the president, shall function to document the qualifications, compliance, and credentials of reciprocity candidates.~~ The Application Review Committee shall consist of at least three board members appointed by the president. The committee reviews applications referred by the administrative officers and submits its recommendations to the full board.

D. – F. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004, amended LR

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§113. Rulemaking Procedures

A. Petitions from Interested Persons

1. ~~All petitions, whether requesting the adoption, amendment, or repeal of a rule shall be submitted in written form on plain white bond paper which is letter size (8 1/2" by 11"). The text shall be framed with a margin of at least one inch on all sides, shall have a pitch of not less than 10 characters per inch, and shall be double-spaced; provided however that quotations may be single-spaced as may other matter customarily presented in that manner.~~ All petitions for the adoption, amendment, or repeal of a rule shall be submitted in writing. Petitions must be legibly printed or typed and delivered to the Board office by United States Postal Service, another delivery service (including electronic mail), or by personal delivery.

A.2. – C.1. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 49:953.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:586 (April 2020), amended LR

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Chapter 3. Board Hearings

§301. Board Hearing Procedures and Jurisdiction

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

B. - D. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004, amended LR

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Chapter 5. Pharmacists

§505. Licensure

A. - A.1.b. …

2. Expired License. A pharmacist license that has not been renewed by December 31 of each year shall expire and be null and void. The holder of an expired license may submit a written request, complete with any supporting documentation, for reinstatement to the board. The request may be referred preliminarily to the board's reinstatement committee for an informal hearing and recommendation that may be considered by the board at its next regularly scheduled meeting. The board may reinstate an expired license upon payment of applicable annual, delinquent, and lapsed license fees pursuant to ~~R.S. 37:1184, as amended,~~ Section 115 of this Part and other conditions as the board deems appropriate.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004, LR 33:1124 (June 2007), LR 38:1234 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:1227 (September 2020), amended LR

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§507. Continuing Education Program

A. - B.4. …

C. Requirements

1. A minimum of 1 1/2 ACPE or board-approved CPE units, or 15 hours, shall be required each year as a prerequisite for pharmacist licensure renewal. Of this number, no less than 3/10 ACPE or board-approved CPE units, or three hours, shall be acquired through live presentations, as designated by ACPE or the board. Alternatively, should a pharmacist choose to not acquire at least 3/10 ACPE or board-approved CPE units, or three hours, through live presentations, then he shall acquire an additional 5/10 ACPE or board-approved CPE units, or five hours, through any other acceptable method, over and above the minimum requirement, for a total of two ACPE or board-approved CPE units, or 20 hours.

a. The board accepts Interprofessional Continuing Education (IPCE) credit awarded by a provider with Joint Accreditation (JA), for the purpose of meeting the continuing education requirements for renewal.

b. Nuclear pharmacists shall complete at least five hours of their required continuing education related to applications and procedures specific to nuclear pharmacy.

c. Pharmacists who perform sterile compounding shall complete at least one hour of their required continuing education related to sterile drug preparation, dispensing, and utilization.

d. Pharmacists who administer medications shall complete at least one hour of their required continuing education related to medication administration.

C.2. – D.3. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1306 (October 1997), LR 29:2083 (October 2003), effective January 1, 2004, LR 33:1125 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 46:569 (April 2020), amended LR

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Chapter 9. Pharmacy Technicians

§907. Scope of Practice

A. - A.1. …

B. Pharmacy technician candidates shall not:

1. - 3. …

4. compound ~~high risk~~ Category 3 sterile preparations, as defined by the United States Pharmacopeia (USP), or ~~its successor;~~ compound sterile preparations from nonsterile starting ingredients.

B.5. - C.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005, amended LR 32:1049 (June 2006), amended by the Department of Health, Board of Pharmacy, LR 43:2498 (December 2017), effective January 1, 2018, amended LR 48:496 (March 2022), amended LR 49:1558 (September 2023), amended LR

§909. Continuing Education

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

1. The board accepts Interprofessional Continuing Education (IPCE) credit awarded by a provider with Joint Accreditation (JA), for the purpose of meeting the continuing education requirements for renewal.

2. Certified pharmacy technicians who perform sterile compounding shall complete at least one hour of their required continuing education related to sterile drug preparation, dispensing, and utilization.

3. Certified pharmacy technicians who administer medications shall complete at least one hour of their required continuing education related to medication administration.

B. – D.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2487 (November 2004), effective January 1, 2005, amended LR 39:1778 (July 2013), amended by the Department of Health, Board of Pharmacy, LR 43:2498 (December 2017), effective January 1, 2018, amended LR

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Chapter 11. Pharmacies

Subchapter A. General Requirements

§1103. Prescription Department Requirements

A. - G. …

H. References. ~~The current edition of the Louisiana Board of Pharmacy Laws and Regulations shall be maintained and readily available within the prescription department of a pharmacy. The pharmacy shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice, including but not limited to, veterinary pharmacy.~~ Each pharmacy permit shall maintain access to current versions of the following:

1. applicable state and federal pharmacy laws and regulations; and

2. relevant reference materials applicable to the pharmacy's scope of practice.

I. - J. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022), LR 49:1556 (September 2023), amended LR 50:1156 (August 2024), amended LR

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Subchapter B. Pharmacy Records

§1119. Definitions

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

* * *

~~*Password*—a private identification that is created by a user to obtain access to an electronic pharmacy information system.~~ – Repealed.

~~*Personal Identifier*—a unique user name or number for identifying and tracking a specific user's access to a pharmacy information system such as Social Security number, user identification number, or employee number.~~ - Repealed

Positive Identification— means a secure, unique, and verifiable method that indisputably links a practice of pharmacy activity or other function recorded in a pharmacy information system to the specific pharmacist, pharmacy intern, pharmacy technician, pharmacy technician candidate, or other personnel who performed the activity.

~~a method of identifying an individual who prescribes, administers, or dispenses a prescription drug.~~

~~a. A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:~~

~~i. a manual signature on a hard copy record;~~

~~ii. a magnetic card reader;~~

~~iii. a bar code reader;~~

~~iv. a thumbprint reader or other biometric method;~~

~~v. a proximity badge reader;~~

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

~~vii. a printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the prescription drug. The printout must be maintained for two years and made available on request to an agent of the board.~~

~~b. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), LR 29:2090 (October 2003), effective January 1, 2004, LR 40:2252 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020), amended LR

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§1123. Records of Prescription Drug Orders and Chart Orders

~~A. There shall be positive identification of the pharmacist, intern, technician, or technician candidate responsible for performing all activities related to the practice of pharmacy including, but not limited to:~~

~~1. prescription information entered into the pharmacy information system;~~

~~2. prospective drug utilization review;~~

~~3. prescription dispensing;~~

~~4. administration of immunizations.~~

~~B. A pharmacy may use one of the following types of pharmacy information systems.~~

~~1. A system that utilizes the original hard copy prescription or chart order to document the initial dispensing, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system shall require the manual signature or initials of a pharmacist on a hard copy record as specified in Subsection E of this Section.~~

~~2. an electronic recordkeeping system that complies with the provisions of 21 CFR 1311 et seq. and documents the positive identification of the pharmacist responsible for the practice of pharmacy. Such systems shall provide for routine backups at least once per day.~~

~~C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard copy printout or other mutually agreeable transfer media) of patient profile information for all prescriptions drug orders and chart orders dispensed within the previous two years. This information shall include the following minimum data:~~

~~1. the original prescription number;~~

~~2. date of issuance of the original prescription drug order or chart order by the prescriber;~~

~~3. date of dispensing by the pharmacist;~~

~~4. full name and address of the patient;~~

~~5. full name and address of the prescriber;~~

~~6. directions for use;~~

~~7. the name, strength, dosage form, and quantity of the drug prescribed;~~

~~8. the quantity dispensed if different from the quantity prescribed;~~

~~9. the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in Section 515 of this Part, and the pharmacist responsible for dispensing;~~

~~10. the total number of refills authorized by the prescriber; and~~

~~11. the refill history of the prescription as defined in Subsection D of this Section.~~

~~D. The refill history of the prescription record maintained in the pharmacy information system shall include, but is not limited to:~~

~~1. the prescription number;~~

~~2. the name and strength of the drug dispensed;~~

~~3. the date of the refill or partial fill;~~

~~4. the quantity dispensed;~~

~~5. the pharmacist responsible for prospective drug utilization review as defined in Section 515 of this Part, and the pharmacist responsible for dispensing each refill;~~

~~6. the total number of refills or partial fills dispensed to date for that prescription order.~~

~~E. The hard copy documentation required pursuant to Paragraph B.1 of this Section shall be provided by each individual pharmacist who makes use of such system by signing a statement attesting to the fact that the prescription information entered into the computer is correct as displayed.~~

A. Positive Identification. All pharmacy activities related to the practice of pharmacy, including but not limited to prescription entry, prospective drug utilization review, dispensing, and administration, shall be documented in the pharmacy information system with positive identification, as defined in Section 1119 of this Chapter, of the responsible pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate.

B. Pharmacy Information System. The pharmacy information system shall maintain complete and accurate records of all prescription and chart orders dispensed within the past two years. Such records shall be searchable by patient, prescriber, drug, and dispensing date, and shall be immediately retrievable in both printed and downloadable electronic formats. At a minimum, each record shall include:

1. prescription number;
2. date of issuance and date(s) of dispensing, including refills and partial fills;
3. patient name and address;
4. prescriber name and address;
5. directions for use;
6. drug name, strength, dosage form, and quantity prescribed;
7. quantity dispensed for each fill;
8. positive identification(s) of responsible pharmacy staff;
9. total number of refills authorized; and
10. a complete refill history, including the total number of refills or partial fills dispensed to date.

~~F.~~ C. Backup ~~Support~~ System

1. ~~The pharmacy information system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.~~ Pharmacies shall perform a backup of the pharmacy information system at least once daily and ensure that all dispensing conducted during system downtime is documented and entered into the system upon its restoration.

~~2. In the event the pharmacy information system experiences down time, a record of all refills dispensed during such time shall be recorded and then entered into the pharmacy information system as soon as it is available for use. During the time the pharmacy information system is not available, prescriptions drug orders and chart orders may only be refilled if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.~~

~~G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable transfer media) of information for all prescription drug orders or chart orders filled or refilled within the previous two years. This information shall include, at a minimum, the following data:~~

~~1. pharmacy name and address;~~
~~2. original prescription number;~~
~~3. date of issuance of the original prescription drug order or chart order by the prescriber;~~
~~4. date of original dispensing by the pharmacist;~~
~~5. full name and address of the patient;~~
~~6. full name and address of the prescriber;~~
~~7. directions for use;~~
~~8. name, strength, dosage form, and quantity of the drug prescribed;~~
~~9. quantity dispensed if different from the quantity prescribed;~~
~~10. total number of refills authorized by the prescriber;~~
~~11. total number of refills dispensed to date for that prescription drug order or chart order;~~
~~12. date of each refill;~~

~~13. name or initials of each individual dispensing pharmacist.~~

~~H.~~ D. Change Log. A log shall be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. At a minimum, the log shall contain the following information:

1. date and time of change;
2. change(s) made;
3. pharmacist making the change.

~~I. Prescription drug orders and chart orders entered into a pharmacy information system but not dispensed shall meet all of the following requirements:~~

~~1. the complete prescription information shall be entered in the computer system;~~

~~2. the information shall appear in the patient's profile; and~~

~~3. there is positive identification, in the pharmacy information system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system.~~

~~J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the pharmacy, or written prescription drug orders or chart orders received by facsimile in the pharmacy, or written prescriptions drug orders or chart orders presented to the pharmacy, a pharmacy may use an electronic imaging system to preserve such prescriptions, but only if:~~

~~1. the system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription form and its annotations;~~

~~2. any notes of clarification of and alterations to a prescription shall identify the author and shall be directly associated with the electronic image of the prescription form;~~

~~3. the image of the prescription form and any associated notes of clarification to or alterations to a prescription are retained for a period of not less than two years from the date the prescription is last dispensed;~~

~~4. policies and procedures for the use of an electronic imaging system are developed, implemented, reviewed, and available for board inspection; and~~

~~5. the prescription is not for a controlled dangerous substance.~~

~~K.~~ E. Filing and Retention ~~of Prescription Forms~~

1. Hard copy prescriptions and chart orders shall be stored in numerical or date sequence; Schedule II drugs filed separately. ~~Written prescription drug order or chart order forms (including transcriptions of verbal prescriptions received in the pharmacy, prescription drug orders or chart orders received by facsimile in the pharmacy, as well as written prescription drug order or chart order forms presented to the pharmacy) shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These original hard copy prescription drug order and chart order forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.~~

a. Electronic imaging retention of oral, faxed, or written prescriptions is permitted and may replace paper retention if the system captures and preserves exact images of both the front and back, and retains records for at least two years after the most recent transaction; controlled substances are excluded unless in conformance with 21 CFR Parts 1300-1399.

2. ~~For those pharmacies utilizing an electronic imaging system as described in Subsection J of this Section, written prescription drug order forms may be disposed of in a manner which protects the confidentiality of protected~~

~~health information.~~ Electronic prescriptions must be retained for at least two years after the most recent transaction; hard copies optional.

~~3. Prescription drug order and chart order forms received as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system for a minimum of two years following the most recent transaction. Further, the pharmacy may produce a hard copy of the prescription drug order form but shall not be required to do so merely for recordkeeping purposes.~~

~~4. Electronic prescription drug orders and chart orders, those generated electronically by the prescriber, transmitted electronically to the pharmacy, and then received electronically directly into the pharmacy information system, shall be retained within the information system for a minimum of two years following the most recent transaction. The pharmacy may produce a hard copy of the prescription drug order or chart order, but shall not be required to do so merely for recordkeeping purposes.~~

~~L.~~ F. Patient Profiles. Pharmacies shall maintain retrievable patient profiles, including but not limited to patient demographics, allergies, conditions, medications, and prescription history. Pharmacists shall ensure the accuracy of these records. ~~All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.~~

~~1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, document, and maintain at least the following records:~~

~~a. the patient's data record, which should consist of, but is not limited to, the following information:~~

~~i. full name of the patient for whom the drug is intended;~~

~~ii. residential address and telephone number of the patient;~~

~~iii. patient's date of birth;~~

~~iv. patient's gender;~~

~~v. a list of current patient specific data consisting of at least the following:~~

~~(a). known drug related allergies;~~

~~(b). previous drug reactions;~~

~~(c). history of or active chronic conditions or disease states;~~

~~(d). other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices;~~

~~vi. the pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug;~~

~~b. The patient's drug therapy record, which shall contain at least the following information for all the prescription drug orders and chart orders that were filled at the pharmacy:~~

~~i. name and strength of the drug or device;~~

~~ii. prescription number;~~

~~iii. quantity dispensed;~~

~~iv. date dispensed;~~

~~v. name of the prescriber;~~

~~vi. directions for use;~~

~~c. any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, LR 36:755 (April 2010), LR 40:2253 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020), LR 47:1643 (November 2021), amended LR

§1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other than Hospitals - Repealed.

~~A. Definitions~~

~~*Electronic Drug Record Keeping System*—a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.~~

~~*Inpatient*—a person receiving health care services within a healthcare facility other than a hospital licensed by the department.~~

~~*Password*—a private identification that is created by a user to obtain access to an electronic drug record keeping system.~~

~~*Personal Identifier*—a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as Social Security number, user identification number, or employee number.~~

~~*Positive Identification*—~~

~~a. has the same meaning as defined in Section 1119 of this Chapter, except that a specific facility having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:~~

~~i. adequate audit controls are in place to detect and deter drug diversion;~~

~~ii. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;~~

~~iii. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;~~

~~iv. an ongoing quality assurance program is in place to ensure that Clauses i through iii of this term are being fulfilled and reviewed; and~~

~~v. appropriate policies and procedures are in place to address Clauses i through iv of this term;~~

~~b. all of the above notwithstanding, however, positive identification as defined in Section 1119 of this Chapter shall always be used to document the:~~

~~i. dispensing, compounding, or prepackaging of a drug;~~

~~ii. removal and possession of a controlled substance to administer to a patient; and~~

~~iii. waste of a controlled substance.~~

~~B. Drug Distribution and Control. The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs.~~

~~1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and efficient distribution of medications and pharmacy care. A current copy of the manual shall be available for board inspection upon request.~~

2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual inventory of all controlled dangerous substances within his span of control, in compliance with the provisions of Section 2733 of this Part.

3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:

a. a record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured;

b. all drug orders and records relating to the practice of pharmacy:

i. Records of drugs dispensed shall include, but are not limited to:

(a). the name, strength, and quantity of drugs dispensed;

(b). the date of dispensing;

(c). the name of the inpatient to whom, or for whose use, the drug was dispensed; and

(d). positive identification of all pharmacists involved in the dispensing;

ii. all other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:

(a). the name of the inpatient to whom, or for whose benefit, the activity was performed;

(b). the nature of the pharmacy practice activity performed;

(c). the results of the activity, if applicable; and

(d). positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist;

iii. Records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of this Chapter.

c. A record of all drugs compounded or prepackaged for use only within a healthcare facility, which shall include at least the following:

i. name of drug, strength, quantity, and dosage form;

ii. manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);

iii. manufacturer's or distributor's name, if a generic drug is used;

iv. pharmacy control number;

v. manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);

vi. pharmacy's expiration date or beyond-use date;

vii. identification of the licensed person responsible for the compounding or prepackaging of the drug;

d. a record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:

i. the name, strength, dosage form, and amount of the drug distributed;

ii. the area receiving the drug;

iii. the date distributed;

iv. identification of the individual receiving the drug if it is a controlled dangerous substance;

v. the area of the facility receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:

(a). name of the patient;

(b). name, dosage form, and strength when applicable of the drug;

~~(c). date and time the drug was administered;~~

~~(d). quantity administered;~~

~~(e). positive identification of the personnel administering the drug;~~

~~e. a log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:~~

~~i. date and time of change;~~

~~ii. changes made;~~

~~iii. person making the change.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 40:2255 (November 2014), effective January 1, 2015, amended by Department of Health, Board of Pharmacy, LR 46:582 (April 2020), repromulgated LR 46:694 (May 2020), Repealed LR

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Chapter 12. Automated Medication Systems

§1203. Automated Medication System Registration

A. – B.3. …

C. Application for Initial Issuance of Registration

1. ...

2. The application shall be accompanied by payment of the registration fee authorized by ~~R.S. 37:1184~~ Section 115 of this Part.

3. – 5. …

D. Maintenance of Registration

1. ...

2. ~~A duplicate or replacement registration shall be issued upon the written request of the owner of the registration and payment of the fee authorized by R.S. 37:1184. A duplicate or replacement registration shall be marked as such, and it shall not serve or be used as an additional or second registration.~~

~~3.~~ In the event a pharmacy intends to relocate an automated medication system to a different address, the pharmacy shall notify the board of its intent to do so, providing both current and new addresses. A change in business address may require an inspection by the board or its designee.

E. Application for Renewal of Registration

1. The pharmacy shall complete an application for the renewal of the registration and submit it to the board prior to the expiration date of the registration. The application shall be accompanied by the fee authorized by ~~R.S. 37:1184~~ Section 115 of this Part.

E.2. – F.2. …

G. Application for Reinstatement of Suspended or Revoked Registration

1. …

2. The applicant shall complete an application form for this specific purpose supplied by the board and shall attach any documentation requested by the board and fees identified in ~~R.S. 37:1184~~ Section 115 of this Part.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000), effective July 1, 2000, amended LR 38:1235 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 47:241 (February 2021), amended LR

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Chapter 15. Hospital Pharmacy

§1503. Definitions

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

* * *

Electronic Drug Record Keeping System ~~– a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug~~. – Repealed.

* * *

Password— ~~a private identification that is created by a user to obtain access to an electronic drug record keeping system.~~ - Repealed.

Personal Identifier— ~~a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as Social Security number, user identification number, or employee number.~~ - Repealed.

Positive Identification— means a secure, unique, and verifiable method that indisputably links a practice of pharmacy activity or other function recorded in a pharmacy information system to the specific pharmacist, pharmacy intern, pharmacy technician, pharmacy technician candidate, or other personnel who performed the activity.

~~1. has the same meaning as defined in Section 1119 of this Part, except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist in charge has determined:~~

~~a. adequate audit controls are in place to detect and deter drug diversion;~~

~~b. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;~~

~~c. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;~~

~~d. an ongoing quality assurance program is in place to ensure that all three provisions cited above in this definition are being fulfilled and reviewed; and~~

~~e. appropriate policies and procedures are in place to address all four provisions cited above in this definition;~~

~~2. All of the above notwithstanding, however, positive identification as defined in Section 1119 of this Part shall always be used to document the:~~

~~a. dispensing, compounding, or prepackaging of a drug;~~

~~b. removal and possession of a controlled substance to administer to a patient; and~~

~~c. waste of a controlled substance.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 33:1132 (June 2007), LR 39:1282 (May 2013), LR 40:2256 (November 2014), effective January 1, 2015, LR 41:2147 (October 2015), amended by Department of Health, Board of Pharmacy, LR 46:582 (April 2020), amended LR 46:793 (June 2020), amended LR

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§1525. Hospital Off-Site Satellite Pharmacy

A. Issuance and Maintenance of Permit

1. – 2. …

3. The applicant shall pay the fee for the initial issuance and renewal as specified in ~~R.S. 37:1184~~ Section 115 of this Part.

A.4. – B.8. …

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:1283 (May 2013), amended by Department of Health, Board of Pharmacy, LR 46:583 (April 2020), amended LR

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Chapter 18. Correctional Center Pharmacy

§1803. Permit Application Procedures

A. Application for Initial Issuance of Permit

1. The applicant for a correctional center pharmacy permit shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in ~~R.S. 37:1184~~ Section 115 of this Part, to the board.

A.2. – C.2. …

C.3. An application for the reinstatement of an expired permit shall be referred to the board's reinstatement committee for consideration. ~~a permit which has been expired:~~

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

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

~~c. more than five years may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.~~

4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by ~~R.S. 37:1184~~ Section 115 of this Part.

D. – D.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020), amended LR

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§1811. Definitions - Repealed

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

Emergency Drug Kit (EDK)— ~~a container holding designated emergency drugs which may be required to meet the immediate therapeutic needs of an offender.~~ – Repealed.

Emergency Drugs— ~~those drugs which may be required to meet the immediate therapeutic needs of an offender and which are not available from any other authorized source in sufficient time to prevent risk of harm to the offender because of a delay resulting from obtaining such medications from such other source.~~ —Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 May 2012), repromulgated by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020), repealed LR

§1813. Emergency Drug Kit Permit – Repealed

~~A. A correctional center pharmacy located outside a correctional center intending to use one or more emergency drug kits within the correctional center shall first obtain an EDK permit from the board.~~

~~B. Application for Initial Issuance of Permit~~

~~1. The correctional center pharmacy shall apply to the board for the permit.~~

~~2. The applicant shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184, to the board.~~

~~3. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.~~

~~4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.~~

~~C. Application for Renewal of Permit~~

~~1. Without respect to the date of initial issuance, an EDK permit shall expire at midnight on June 30 of every year, unless relinquished, surrendered, suspended, or revoked sooner in accordance with the Pharmacy Practice Act or this Part.~~

~~2. An EDK shall not be maintained or used with an expired permit.~~

~~3. The correctional center pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.~~

~~4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.~~

~~D. Application for Reinstatement of Expired Permit~~

~~1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.~~

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

~~3. An application for the reinstatement of an EDK permit which has been expired:~~

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

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

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

~~4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184.~~

~~E. Maintenance of Permit~~

~~1. EDK permits are specific to a correctional center and to a correctional center pharmacy and they are not transferable.~~

~~2. In the event multiple kits are required for a correctional center, a separate permit shall be required for each EDK.~~

~~3. The original EDK permit shall be displayed in the correctional center pharmacy supplying the EDK, and a copy of the permit shall be maintained in the room or area where the EDK is located.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:573 (April 2020), repealed LR

§1815. Emergency Drug Kit Requirements - Repealed

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

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

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

~~1. drug name;~~

~~2. dosage form;~~

~~3. drug strength;~~

~~4. name of manufacturer and/or distributor;~~

~~5. manufacturer's lot or batch number; and~~

~~6. expiration date, according to relevant standards from the United States Pharmacopeia (USP).~~

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

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

~~F. When an authorized prescriber issues an order for the administration of a drug contained within the EDK, the order and proof of use shall be delivered in written or electronic format to the correctional center pharmacy; further, such records shall contain the following minimum information:~~

~~1. name of offender;~~

~~2. drug name, strength, and quantity;~~

~~3. nature of the emergency;~~

~~4. time and date of administration;~~

~~5. name of prescriber authorizing the medication; and~~

~~6. name of person administering the medication.~~

~~G. The correctional center pharmacy shall inspect the EDK periodically, but in no event more than 30 days after the previous inspection. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained by the correctional center pharmacy and available for review by the board or its agents.~~

~~H. The EDK shall be available for inspection by the board or its agents.~~

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:573 (April 2020), repealed LR

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Chapter 25. Prescriptions, Drugs, and Devices

Subchapter C. Compounding of Drugs

§2533. Definitions

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

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

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

* * *

Cytotoxic—~~any pharmaceutical that has the capability of killing living cells.~~ *Repealed*

* * *

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

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, LR 41:97 (January 2015), amended LR

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Chapter 30. Pharmacy Benefit Managers

§3005. Permitting Procedures

A. – C.2. …

D. Maintenance of Permit

1. ...

2. ~~Upon receipt of a written request and payment of the fee authorized in R.S. 37:1184, the board shall issue a duplicate or replacement permit to the applicant; however, such duplicate or replacement permit shall not serve or be used as an additional or second permit.~~

E. – E.2. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1253.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:591 (May 2021), amended LR 48:2105 (August 2022), amended LR 49:1557 (September 2023), amended LR