NOTICE OF INTENT

Department of Health
Board of Pharmacy

Prescriptions (LAC 46:LIII.2511 and 2519)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy hereby gives notice of its intent to amend §2511 and §2519 of its rules relative to prescriptions. The proposed Rule changes in §2511 clarify the definition of an electronic prescription, define practitioner, add a description of patient authority to acquire a prescription drug or device, add a requirement for pharmacies to transfer filled and unfilled prescriptions when requested by the patient, add a definitive list of practitioners authorized to issue prescriptions, address clarification of information required on prescriptions and allow prescription adaptation by the pharmacist. The proposed Rule changes in §2519 prohibit pharmacies from requesting refill authorization from the prescriber in the absence of a request from the patient, his agent, or his caregiver and clarify that pharmacies may offer their patient an auto-refill service to facilitate refill requests. The implementation of the proposed Rule changes caused a reorganization of lettering in the sections.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 25. Prescriptions, Drugs, and Devices
Subchapter B. Prescriptions
§2511. Prescriptions and Chart Orders

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

* * *

Electronic Prescription—a prescription generated, signed, and transmitted in electronic form, excluding electronically transmitted facsimile documents.

Practice Affiliation—repealed.

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

* * *

B. Patient Authority to Acquire Prescription Drug or Device

1. A prescription or chart order represents the lawful authority for a patient, or his agent or caregiver, to acquire a prescription drug or device from a pharmacy licensed to dispense prescription drugs and devices.

2. In the absence of refill instructions on the original prescription, the prescription shall not be refilled. A pharmacist, using his professional judgment, may dispense the total quantity authorized in one transaction, or in the alternative, may dispense partial quantities in multiple transactions, provided however, that the sum of the partial quantities shall not exceed the total quantity authorized.

3. In the event a prescription contains refill instructions, the prescription may be refilled when requested by the patient, or his agent or caregiver. A pharmacist, using his professional judgment, may dispense the quantity authorized for each refill in a single transaction, or in the alternative, may dispense partial quantities in multiple transactions, provided however that the sum of the partial quantities shall not exceed the total quantity authorized.

4. While the documentation of a prescription or chart order shall be retained by the dispensing pharmacy as evidence of its lawful dispensing of the prescription drug, the patient's lawful authority to obtain the drug conveyed by the prescription or chart order shall continue to exist until the earliest of the expiration date of the prescription or chart order, or in the alternative, when the total quantity authorized has been dispensed.

5. In the event a patient, or his agent or caregiver, requests a pharmacy to transfer an unfilled prescription for a medication not listed as a controlled substance to another pharmacy, the pharmacy shall comply with that request as soon as possible, but no later than the end of the next business day.

6. In the event a patient, or his agent or caregiver, requests a pharmacy to transfer the remainder of an unexpired prescription to another pharmacy, the pharmacy shall transfer that prescription information in compliance with the provisions of this Chapter as soon as possible but no later than the end of the next business day. Prior to such transfer, a pharmacy shall not cancel the remainder of an unexpired prescription unless such action is required by law or rule or is requested by the prescriber.

C. Persons Authorized to Issue Prescriptions and Chart Orders

1. A prescription for a drug or device may be issued by a practitioner with valid prescriptive authority.

2. A prescription may be prepared by the agent of the prescriber for the signature of the prescriber, but the prescriber retains accountability for the proper issuance of a valid prescription. A prescriber's agent may communicate a valid prescription to a pharmacy.

3. A pharmacist may issue a prescription when so authorized by law, rule, standing order, or practice agreement.

D. Required Information

1. A prescription shall contain the following data elements:

a. prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;

b. patient's name, and if for a controlled substance, address;

c. date prescription issued by the prescriber;

d. name of drug or device, and if applicable, strength, and quantity to be dispensed;

e. directions for use;

f. signature of the prescriber; and

g. refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.

2. In the event a pharmacist receives a prescription or chart order lacking certain required information, the pharmacist, pharmacy intern or certified pharmacy technician may consult with the prescriber or his agent to clarify the prescriber's intent.

E. Manner of Issuance

1. Oral Prescriptions

a. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system.

b. In the event a pharmacy intern or pharmacy technician transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.

2. Written Prescriptions. A written prescription shall conform to the following format.

a. The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a single printed signature line.

b. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling, the authorized prescriber's printed name.

c. No prescription form shall contain more than four active prescription drug orders. Each active prescription drug order on the form shall provide the following:

i. check box labeled "Dispense as Written", or "DAW", or both; and

ii. the number of refills, if any.

d. The prescription shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner on the date issued and in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Examples of invalid signatures include rubber stamps,

signatures of anyone other than the prescriber, and computer-generated signatures.

e. Receipt via Facsimile

i. Pharmacies may elect to receive written prescriptions via a facsimile machine located within the prescription department. The paper used to print such prescriptions shall produce a non-fading image. The pharmacy may elect to scan such documents in compliance with §1123 of this Part.

ii. Pharmacies may elect to receive written prescriptions via electronic facsimile directly within their pharmacy information system. The pharmacy shall retain such records in compliance with Section 1123 of this Part.

f. Chart orders and forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed in this Section.

3. Electronic Prescriptions

a. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the DEA registration number.

F. Prescription Adaptation

1. With the consent of the patient, or his agent or caregiver, a pharmacist may adapt a prescription drug order or chart order unless the prescriber has indicated adaptation is not permitted, subject to the following limitations:

a. A pharmacist may change the quantity of medication prescribed if:

i. the prescribed quantity or package size is not commercially available;

ii. the change in quantity is related to a change in dosage form;

iii. the change is intended to dispense up to the total amount authorized by the prescriber; or

iv. the change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.

b. A pharmacist may change the dosage form of the medication prescribed if it is in the best interest of patient care; however, the pharmacist shall modify the prescriber's directions to ensure an equivalent amount of the medication prescribed is dispensed.

c. A pharmacist may add information missing on the prescription drug order or chart order if there is evidence to support the change.

d. A pharmacist who adapts a prescription drug order or chart order shall document the adaptation in the patient's record.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004, LR 41:98 (January 2015), LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 43:2162 (November 2017), LR 46:585 (April 2020), LR 47:1644 (November 2021), amended LR 49:

§2519. Prescription Refills; Medication Synchronization and Refill Consolidation

A. Prescription Refills

1. Limitations on Number of Refills

a. The refilling of a prescription for a drug listed in Schedule II is prohibited.

b. A prescription for a drug listed in Schedule III or IV may be refilled up to five times if so indicated at the time issued.

c. A prescription for a drug listed in Schedule V may be refilled without limitation if so indicated at the time issued subject to the one-year expiration date of the prescription.

d. A prescription for a drug not listed as a controlled substance or for a medical device, medical gas, or durable medical equipment may be refilled without limitation if so indicated at the time issued subject to the one year expiration date of the prescription.

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

3. Patient Request for Continuation of Therapy. When previously authorized refills have been dispensed, or when the previous prescription has expired, and the patient, or his agent or caregiver, requests continuation of therapy, the pharmacy may submit a request to the prescriber for a new prescription. A pharmacy may offer their patient an auto-refill service to facilitate such requests for the life of that prescription. In the absence of a specific request for continuation of therapy from the patient, or his agent or caregiver, the pharmacy shall not submit a request for continuation of therapy to a prescriber.

4. Dispensing of Refills. Prescription refills authorized by the prescriber shall not be dispensed in the absence of a patient, or his agent or caregiver's, request or approval. A pharmacy may offer their patient an auto-refill service to facilitate such requests. This prohibition shall not apply to refills authorized by the prescriber which are to be dispensed to a patient residing in a long-term care facility.

B. Medication Synchronization and Refill Consolidation. These terms refer to a service which a pharmacist may perform for his patient, at the request of the patient, wherein he may proactively adjust the medication dispensing quantity and/or the refill schedule of a prescription in order to manage the patient's medication therapy, with the goal of improved medication adherence by the patient.

1. For the performance of this service, the pharmacist may adjust the dispensing quantity and/or the refill schedule originally ordered by the prescriber; however, the pharmacist shall not exceed the total quantity prescribed [dispensing quantity multiplied by the total number of fills authorized (original plus refills)], or what is otherwise allowed by law.

2. With respect to prescriptions for controlled substances where refills have been authorized, pharmacists may utilize partial fills, as described in §2747.C.5 of this Part, but may not exceed the dispensing quantity noted on the original prescription.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, LR 33:1133 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 42:1519 (September 2016), LR 46:575 (April 2020), LR 47:1644 (November 2021), amended LR 49:

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed Rule changes will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed Rule changes will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed Rule changes will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed Rule changes will have no effect on family earnings and family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed Rule changes will have no effect on the behavior and personal responsibility of children.

6. The Ability of the Family or a Local Government to Perform the Function as Contained in the proposed Rule. The proposed Rule changes will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed Rule changes will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed Rule changes will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed Rule changes will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule changes will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed Rule changes will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed Rule changes will have no effect on compliance or reporting requirements for small businesses.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed Rule changes will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed Rule changes will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed Rule changes will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

5. The Exemption of Small Businesses from All or Any Part of the Requirements Contained in the proposed Rule. There are no exemptions for small businesses in the proposed Rule changes.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed Rule changes will have no effect on the staffing level requirements or qualifications required to provide the same level of service.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed Rule changes will have no effect on the cost to the provider to provide the same level of service.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed Rule changes will have no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-

1700. He is responsible for responding to inquiries regarding the proposed Rule amendments. The deadline for the receipt of all written comments is 12 p.m. noon on Tuesday, March 28, 2023.

Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9:00 a.m. on Tuesday, March 28, 2023 at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Prescriptions

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed Rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of $500 in FY 2023 and $500 in FY 2024. There will be no additional expenditures or cost savings to state or local governmental units.

The proposed changes in §2511 clarify the definition of an electronic prescription, define practitioner, add a description of patient authority to acquire a prescription drug or device, add a requirement for pharmacies to transfer filled and unfilled prescriptions when requested by the patient, add a definitive list of practitioners authorized to issue prescriptions, address clarification of information required on prescriptions and allow prescription adaptation by the pharmacist. The proposed Rule changes in §2519 prohibit pharmacies from requesting refill authorization from the prescriber in the absence of a request from the patient, his agent, or his caregiver and clarify that pharmacies may offer their patient an auto-refill service to facilitate refill requests.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed Rule changes will not affect revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The proposed Rule changes in §2511 affect consumers by defining the patient's authority to acquire a prescription drug or device, requiring pharmacies to transfer filled and unfilled prescriptions when requested by the patient, and allowing for prescription adaptation by the pharmacist. This documents the patient's lawful authority to obtain the drug conveyed by the prescription and prevents the cancellation of the prescription unless required by law or rule or requested by the prescriber. This also allows a pharmacist to adapt certain elements of a prescription, unless prohibited by the prescriber, and to add information missing on the prescription if there is evidence to support the change.

The proposed Rule changes in §2519 affect consumers and prescribers by prohibiting the pharmacy from requesting refill authorization from the prescriber in the absence of a request from the patient, his agent, or his caregiver, while allowing the pharmacy to offer their patient an auto-refill service to facilitate refill requests. This will result in a decrease in the number of refill requests submitted to prescribers without patient knowledge and could result in a reduction in healthcare waste from unwanted prescriptions being filled.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed Rule changes will have no effect on competition or employment.

M. Joseph Fontenot, Jr.
Executive Director
2302#022

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office