

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov



February 3, 2023

Senator P. Page Cortez President, Louisiana Senate

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail - Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2023-01 ~ Prescriptions

Dear Senator Cortez:

The Board seeks 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.

In connection with this regulatory project, the following items are appended:

Notice of Intent
 Page 2

Fiscal & Economic Impact Statement

Page 9

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Tuesday, March 28, 2023 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr. Executive Director

cc: Chair, Senate Health & Welfare Committee

Via Email: APA.S-H&W@legis.la.gov

Speaker, House of Representatives

Via Email: APA.HouseSpeaker@legis.la.gov

Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov

Director, Community Competitiveness & Small Business Services, La. Economic Development

Via Email: Witty@la.gov

Editor, Louisiana Register

Via Email: Reg.Submission@la.gov

Reference File

NOTICE OF INTENT

Department of Health Board of Pharmacy

Prescriptions (LAC 46:LIII.2511, 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

§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—a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine.

<u>Practitioner</u> – 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
 - 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.

 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.

-B D. Requirements Required Information.

- <u>1</u>. A prescription shall contain the following data elements:
 - 4 <u>a</u>. Prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;
 - 2 b. Patient's name, and if for a controlled substance, address;
 - $3 \underline{c}$. Date prescription issued by the prescriber;
 - 4 d. Name of drug or device, and if applicable, strength, and quantity to be dispensed;
 - 5 e. Directions for use;
 - $6 \underline{f}$. Signature of the prescriber; and
 - 7 g. Refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.
- 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

- D. 1. Oral Prescriptions.
 - 4 <u>a</u>. 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.
 - <u>b.</u> 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.
- C. 2. Written Prescriptions. A written prescription shall conform to the following format:

- 4 <u>a.</u> The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a single printed signature line.
- 2 <u>b</u>. 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.
- 3 c. No prescription form shall contain more than four <u>active</u> prescription drug orders. Each <u>active</u> prescription drug order on the form shall provide the following:
 - a i. check box labeled "Dispense as Written", or "DAW", or both; and
 - $b \underline{ii}$. the number of refills, if any.
- 4 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 computergenerated signatures.
- 5 e. Receipt via Facsimile
 - a 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 nonfading image. The pharmacy may elect to scan such documents in compliance with Section 1123 of this Part.
 - b 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.
- 6 <u>f.</u> Chart orders and forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above in this Section.

D. Oral Prescriptions.

- 1. 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. 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.
- \pm . 3. Electronic Prescriptions.
 - 4 <u>a</u>. 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. Completion of Prescription Orders and Chart Orders. In the event a pharmacist receives a prescription order or chart order lacking certain required information, the pharmacist may consult with the prescriber to clarify the prescriber's intent. Following a consultation with the prescriber and the appropriate documentation thereof on the order:
 - 1. A pharmacist may add the following data elements on the order:
 - a. Patient's address; or
 - b. Drug dosage form.

- A pharmacist may record changes in the following data elements on the order: a. Patient's address; b. Drug strength; c. Quantity prescribed; or d. Directions for use. A pharmacist shall never add or make changes to the following data elements on the order: a. Patient's name; b. Date of issue; Drug name (except for generic interchange as permitted by law); or d. Prescriber signature. 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: 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. 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. A pharmacist may add information missing on the prescription drug order or chart order if there is evidence to support the change. 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), amended LR. §2519. Prescription Refills; Medication Synchronization and Refill Consolidation 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.
- 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.
- B 4. <u>Dispensing of Refills Requests</u>. 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. <u>A pharmacy may offer their patient an auto-refill service to facilitate such requests</u>. 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.

C. Controlled Dangerous Substances.

- 1. The refilling of a prescription for a drug listed in Schedule II is prohibited.
- 2. A prescription for a drug listed in Schedule III or IV may be refilled up to five times, if so indicated at the time issued.
- 3. A prescription for a drug listed in Schedule V may be refilled if so indicated at the time issued subject to the one year expiration date of the prescription.
- <u>DB</u>. 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.
 - With respect to prescriptions for controlled substances where refills have been authorized, pharmacists
 may utilize partial fills, as described in Paragraph 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), amended LR

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.
- 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.

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 Board office. 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. noon 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 GOVERNMENTAL 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, SMALL BUSINESSES, OR NON-GOVERNMENTAL 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.

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

Person Preparing

M. Joseph Fontenot Jr.

Dept.: Dept. of Health

Statement:

Executive Director

Office: Board of Pharmacy

Telephone:

225.925.6481

Prescriptions Title:

Return Address:

3388 Brentwood Drive

Baton Rouge, LA 70809

Effective Date of Rule: Upon promulgation

July 20, 2023 (est.)

SUMMARY (Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND $\underline{\text{WILL}}$ BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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, SMALL BUSINESSES, OR NON-GOVERNMENTAL 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.

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

M. Joseph Fontenot Jr. Digitally signed by M. Joseph Fontenot Jr. Date: 2023.02.01 12:05:15 -06'00'

Signature of Agency Head or Designee

M. Joseph Fontenot Jr, Executive Director

Typed Name and Title of Agency Head

2-2-23Date of Signature

February 1, 2023

Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEFT

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

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. A copy of the notice of intent is appended.

B. Summarize the circumstances which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

In response to a request from the Louisiana State Medical Society to address automated prescription requests, prescription ownership, and transfer of unfilled prescriptions, the Board of Pharmacy determined it appropriate to amend Sections 2511 and 2519 of its rules relative to prescriptions.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session
 - (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated \$1,000 for printing the Notice of Intent and the Rule. LBP operates on self-generated funds.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?				
(a)	Yes. If yes, attach documentation.			
(b) <u>No</u>	NO. If no, provide justification as to why this rule change should be published at this time			

LBP operates on self-generated funds, and they have determined the proposed rule changes are in the public's best interest.

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 23	FY 24	FY 25
Personal Services Operating Expenses Professional Services Other Charges Equipment Major Repairs & Constr.	\$500	\$500	
TOTAL	\$500	\$500	None
POSITIONS (#)	None	None	None

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed rule changes will require LBP to publish the Notice of Intent and Rule in the state register at a cost of \$500 in FY 2023 and \$500 in FY 2024.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 23	FY 24	FY 25
State General Fund Agency Self-Generated Dedicated Federal Funds Other (Specify)	\$ 500	\$500	
TOTAL	\$500	\$500	None

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule changes.

- B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.
 - Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

The proposed rule changes will not result in costs or savings to local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

The proposed rule changes will not affect sources of funding of local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

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

REVENUE INCREASE/DECREASE	FY 23	FY 24	FY 25
State General Fund			
Agency Self-Generated			
Dedicated Funds*			•
Federal Funds			
Local Funds			
TOTAL	None	None	None

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

N/A

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

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.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The proposed rule changes will have no impact on receipts and/or income to these groups.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

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