

## Louisiana Board of Pharmacy

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



July 7, 2022

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 2022-9 ~ Partial Fills of CDS Prescriptions

Dear Senator Cortez:

The Louisiana Board of Pharmacy seeks to amend its rules relative to prescriptions for controlled dangerous substances (CDS). The proposed changes require pharmacies dispensing CDS prescriptions to use a dispensing information system capable of accurately recording partial fills and refills of such prescriptions and also require a pharmacist to dispense a partial fill of a CDS prescription when requested by the patient or prescriber, subject to the pharmacist's obligation relative to corresponding responsibility.

The Board of Pharmacy will use the Department of Justice's Occupational Licensing Review Program (OLRP) to provide active state supervision of this regulatory project. Prior to submitting the second report to the Joint Legislative Oversight Committee on Health & Welfare, the Board will seek OLRP approval. In connection with this regulatory project, the following items are appended:

Notice of Intent
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Fiscal & Economic Impact Statement

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As indicated in the solicitation, we will convene a public hearing on August 26, 2022 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 <a href="mailto:ifontenot@pharmacy.la.gov">ifontenot@pharmacy.la.gov</a> 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**

Partial Fills of Controlled Dangerous Substance Prescriptions (LAC 46:LIII.2735 and 2747)

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 Louisiana Board of Pharmacy hereby gives notice of its intent to amend §§2735 and 2747 of its rules relative to prescriptions for controlled dangerous substances. The proposed change in §2735 require pharmacies dispensing prescriptions for controlled dangerous substances to use a dispensing information system capable of accurately recording partial fills and refills of such prescriptions. The proposed changes in §2747 require a pharmacist to dispense a partial fill of a prescription for a controlled dangerous substance when requested by the patient or prescriber, subject to the pharmacist's obligation relative to corresponding responsibility.

#### Title 46

#### PROFESSIONAL AND OCCUPATIONAL STANDARDS

**Part LIII: Pharmacists** 

#### Chapter 27. Controlled Dangerous Substances

### §2735. Continuing Records

A. ...

- B. Records for Manufacturers, Distributors, Third-Party Logistics Providers, Dispensers, Researchers, Importers, and Exporters
  - 1.-2. ...
  - 3. Records for Dispensers and Researchers.
- <u>a.</u> Each person authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section.
- <u>b.</u> In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.
- <u>c.</u> In addition to the requirements of this Paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription shall also comply with federal law.
- d. Pharmacies dispensing prescriptions for controlled substances shall use a dispensing information system capable of accurately recording partial fills and refills.

B.4. – F.5. ...

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

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

\* \* \*

#### §2747. Dispensing Requirements

A. ...

B. Prescriptions for Controlled Substances Listed in Schedule II

 $1.-4.c.iv \dots$ 

- 5. Partial Filling of Prescription
- a. The partial filling of a prescription for a controlled substance listed in Schedule II is permissible with the following limitations:
  - i. ...
- ii. When a partial fill is requested by the patient or the practitioner who wrote the prescription-prescriber, the pharmacist may shall dispense any quantity less than the total quantity prescribed. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. No partial filling may be dispensed more than 30 days after the date on which the prescription was written. The requirement for a pharmacist to comply with a patient or prescriber request to dispense a partial fill shall not supersede the pharmacist's obligation relative to corresponding responsibility as described in Subsection E of this Section.

5.b. – 8.b.iii. ...

- C. Prescriptions for Controlled Substances Listed in Schedule III, IV, or V
  - 1. 4.c.v. ...
- 5. Partial Filling of Prescriptions. The partial filling of a prescription for a controlled substance listed in Schedules III, IV, or V is permissible, When requested by the patient or prescriber, the pharmacist shall dispense a partial fill of a controlled substance listed in Schedules III, IV or V, provided that:
- a. the information (and the manner in which it is recorded) required for a partial filling, and the manner in which it is recorded, is the same as that required for a refill;
- b. the number of partial fillings is not limited; however, the total quantity dispensed in all partial fillings shall not exceed the total quantity authorized on the original prescription. The total quantity authorized may be calculated as the sum of:
  - i. the quantity prescribed, and
- ii. the calculated amount of the quantity prescribed times the number of refills originally authorized by the prescriber; and
- c. no dispensing shall occur more than six months after the date on which the prescription for a controlled substance listed in Schedule III or IV was issued, or more than one year after the date on which the prescription for a controlled substance listed in Schedule V was issued; and
- d. the requirement for a pharmacist to comply with a patient or prescriber request to dispense a partial fill shall not supersede the pharmacist's obligation relative to corresponding responsibility as described in Subsection E of this Section.

C.6. – F. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008), LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 46:577 (April 2020), LR 47:1645 (November 2021), 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 or 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 or family budget.
- 5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule changes will have no effect on the behavior or 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 rules.

#### **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 or 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 do not establish less stringent compliance requirements for small business.
- 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 do not establish performance 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 Rules.

#### **Public Hearing**

A public hearing to solicit comments and testimony on the proposed rules is scheduled for 9:00 a.m. on Friday, August 26, 2022 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: Partial Fills of Controlled Dangerous Substance 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 \$1,000 in FY 2023. There will be no additional expenditures or cost savings for LBP.

- II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary) The proposed rule changes will not affect revenue collections for 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 modify requirements for pharmacies with regard to partial fills and will affect patients requesting partial fills of prescriptions for controlled dangerous substances by allowing them to obtain a quantity less than that prescribed. The smaller quantity may cost less than the full quantity, would result in a smaller quantity of medication stored or held by the patient, and may result in a smaller quantity of leftover medication available for diversion or destruction.

The proposed rule changes will affect a small number of pharmacies whose dispensing information systems are not currently capable of accurately recording partial fills and refills of prescriptions for controlled dangerous substances. The exact number of pharmacies using outdated software incapable of recording partial fills are unknown though likely minimal given current prescribing standards of practice regarding controlled substances. Currently, pharmacies incapable of recording partial fills must refer the prescription to a separate pharmacy with that capacity or request the prescriber or patient to alter their request from partial to full.

Some pharmacies may see an increase in IT-related costs to adopt compliant software. Information communicated to the Board by pharmacists indicate the vendors of dispensing information software do not usually charge for upgrades to existing software when federal or state regulations require certain capabilities for dispensing information systems. By the Board's rough estimate, 5% of prescriptions filled within Louisiana are partial fills.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

Given the universal nature of the requirement, the proposed rule changes will not affect 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

Title: Partial Fills of Controlled Dangerous

Substance Prescriptions

Return Address:

3388 Brentwood Drive

Baton Rouge, LA 70809

Effective Date of Rule: Upon promulgation

Dec. 20, 2022 (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 WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

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 \$1,000 in FY 2023. There will be no additional expenditures or cost savings for LBP.

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

The proposed rule changes will not affect revenue collections for 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 modify requirements for pharmacies with regard to partial fills and will affect patients requesting partial fills of prescriptions for controlled dangerous substances by allowing them to obtain a quantity less than that prescribed. The smaller quantity may cost less than the full quantity, would result in a smaller quantity of medication stored or held by the patient, and may result in a smaller quantity of leftover medication available for diversion or destruction.

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Some pharmacies may see an increase in IT-related costs to adopt compliant software. Information communicated to the Board by pharmacists indicate the vendors of dispensing information software do not usually charge for upgrades to existing software when federal or state regulations require certain capabilities for dispensing information systems. By the Board's rough estimate, 5% of prescriptions filled within Louisiana are partial fills.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

Given the universal nature of the requirement, the proposed rule changes will not affect competition or employment.

Joe Fontenot

Digitally signed by Joe Fontenot
DN: cn=Joe Fontenot, o=Louislana Board of Pharmacy,
ou=Executive Director, email=Jfontenot@pharmacyJa.gov
c=US
Date: 2022.07.01.12:28:17-05'00'

Signature of Agency Head or Designee

Legislative Fiscal Officer or Designee

M. Joseph Fontenot, Jr., Executive Director

Typed Name and Title of Agency Head

Date of Signature

# FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

July 01, 2022	 
Date of Signature	

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 rule changes in §2735 require pharmacies dispensing prescriptions for controlled substances to use a dispensing information system capable of accurately recording partial fills and refills of such prescriptions. The proposed rule changes in §2747 require a pharmacist to dispense a partial fill of a prescription for a controlled dangerous substance when requested by the patient or prescriber, subject to the pharmacist's obligation relative to corresponding responsibility. 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.

The Board of Pharmacy was made aware of a small number of pharmacy dispensing information systems not capable of accurately recording partial fills of controlled substance prescriptions which prevented patients from obtaining smaller quantities through partial fills. The national and state level efforts to combat the current opioid epidemic by reducing the number of unused opioids in households is undermined when a patient is forced to receive the entire amount of their prescription instead of a partial amount because the pharmacy dispensing information system cannot accommodate a patient or prescriber request for a partial fill.

- 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.

If the answer to (1)				specifically	appropriated	the	funds
necessary for the asso	ociated expend	iture inci	rease?				

(a) \_\_\_\_\_ Yes. If yes, attach documentation.

(b) 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.

## 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	\$1,000		
Operating Expenses Professional Services	, =,		
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$1,000		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 print the Notice of Intent and Rule in the state register at a cost of \$1000 in FY 2023.

## FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

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)	\$1,000		
TOTAL	\$1,000		None

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.

- COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.
  - 1. 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.
  - Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

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

The proposed rule changes do not impact local governmental units.

## 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.

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

<sup>\*</sup>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.
- 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 will affect patients requesting partial fills of controlled substance prescriptions by allowing them to acquire smaller quantities from pharmacies who currently do not have the capability of accurately recording partial fills and refills.

# FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

The proposed rule changes will enable pharmacists, who are currently working with a pharmacy dispensing information system not capable of accurately recording partial fills and refills, to satisfy partial fill requests from patients and prescribers.

The proposed rule changes will affect a small number of pharmacies whose dispensing information systems are not capable of accurately recording partial fills and refills. Information communicated to the Board by pharmacists indicate the software providers do not charge for upgrades to existing software when federal or state regulations place such requirements on the pharmacies.

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 should not impact 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 should not impact competition and employment in the public and private sectors.