Louisiana Board of Pharmacy

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

March 6, 2023

Senator P. Page Cortez
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: **Report No. 2 of 3** for Regulatory Project 2022-9 (Summary Report) ~ Partial Fills of CDS Prescriptions

Dear Senator Cortez:

As we indicated in our first report to your office on July 7, the Board 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 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.

Subsequent to the publication of our *Notice of Intent* in the July 2022 edition of the *Louisiana Register*, we conducted a public hearing on August 26 to receive comments and testimony on the proposed rules. We received one email question regarding the regulatory project which identified an unintended omission in the proposed language contained in the Notice of Intent. After consulting with the Editor of the Register, she noted the omitted language was consistent with the language in the initial preamble presented to the public in the NOI and did not change the meaning. We were instructed by the editor we could proceed with the project. The Board was informed and decided to proceed with the added language. On February 14, 2023 the Department of Justice's Occupational Licensing Review Program determined the proposed amendments had no reasonably foreseeable anticompetitive effects. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the July 2022 *Louisiana Register* – Page 2
- Record from the August 26, 2022 Public Hearing – Page 5
- Full text of proposed rule, as intended for publication in the *Louisiana Register* – Page 10

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rules, as amended, as a Rule in the April 20, 2023 edition of the *Louisiana Register* with an immediate effective date. If you have any questions about the enclosed information or our procedures, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr. Digitally signed by M. Joseph Fontenot Jr.
Date: 2023.03.06 15:07:37 -06'00'

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
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. Record for Dispensers and Researchers

a. 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.

b. 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.

c. 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 48:

§2747. Dispensing Requirements

A. …

B. Prescriptions for Controlled Substances Listed in Schedule II

1. - 4.c. iv …

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 prescriber, the pharmacist shall dispense a 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. 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 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;

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), amended LR 48:

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 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 $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 NONGOVERNMENTAL 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 percent 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.

M. Joseph Fontenot Jr.
Executive Director
2207#060

Alan M. Boxberger
Interim Legislative Fiscal Officer
Legislative Fiscal Office

Louisiana Board of Pharmacy

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

NOTICE IS HEREBY GIVEN that a Public Hearing has been ordered and called for 9:00 a.m. on Friday, August 26, 2022 at the Board office, for the purpose to wit:

AGENDA

Revised 07-07-2022

1. Call to Order 9:00 AM
2. Appearances
3. Solicitation of Comments & Testimony on Proposed Rule Changes
   - A. Regulatory Project 2022-06 ~ Nonresident Pharmacies
   - B. Regulatory Project 2022-07 ~ Licensing Dependents of Healthcare Professionals Relocating to Louisiana
   - C. Regulatory Project 2022-08 ~ Transfer of Prescription Information
   - D. Regulatory Project 2022-09 ~ Partial Fills of CDS Prescriptions
   - E. Regulatory Project 2022-10 ~ Compounding
4. Opportunity for Public Comment
5. Adjourn 12:04 pm

Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ August 26, 2022

Project 2022-6 ~ Nonresident Pharmacies
Project 2022-7 ~ Licensing Dependents of Healthcare Professionals Relocating to Louisiana
Project 2022-8 ~ Transfer of Prescription Information
Project 2022-9 ~ Partial Fills of CDS Prescriptions
Project 2022-10 ~ Compounding

Name	Address	E-mail	Group or Agency Represented
1.			
2.			
3.	NONE		
4.			
5.			

Louisiana Board of Pharmacy

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

August 26, 2022

Public Hearing

Opportunity for Public Comment

1. Name N/A representing _____

   Comments:

2. Name _____ representing _____

   Comments:

3. Name _____ representing _____

   Comments:

4. Name _____ representing _____

   Comments:

5. Name _____ representing _____

   Comments:

From: Michael Yang <misteryaj@gmail.com>
Sent: Sunday, July 17, 2022 4:42 AM
To: info <info@pharmacy.la.gov>
Subject: Re: Notice of Rulemaking Activity (Projects 2022-6 + 2022-7 + 2022-8 + 2022-9 + 2022-10))

Is this the initial partial fill or the completion? As in I wrote Adderall on 7/1/22 with a DNF date of 9/1/22 and can't partial? Or I can't complete a partial fill for the remainder of the partial after the initial 30 days of writing (regardless of dispensed date)?

§2747. Dispensing Requirements
A. ...
B. Prescriptions for Controlled Substances Listed in Schedule II
1. – 4.c.iv ...
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

Louisiana Board of Pharmacy

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

December 12, 2022

Michael A. Yang, PharmD
1260 Capilano Dr
Shreveport, LA 71106-8288
Via E-mail: misteryaj@gmail.com

Re: **Regulatory Project 2022-09 ~ Partial Fills of CDS Prescriptions**

Dear Dr. Yang:

Thank you for your interest in this regulatory project and for taking the time to prepare and submit comments in response to the Public Hearing held on August 26, 2022 relative to the Board's proposed rule amendments. The Board evaluated your comments during their November 16, 2022 meeting and directed this reply to you.

In the email you submitted in regards to the project, you questioned language in the proposed rule amendment which identified an unintended omission.

The Board, after reviewing your email, voted to approve the addition of language originally intended in the proposal in order to clarify its meaning and will continue this regulatory project.

Once again, thank you for your interest in this regulatory project and for taking the time to prepare and submit your comments.

For the Board:

Joe Fontenot
Executive Director

Rule

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 Board of Pharmacy has amended §§2735 and 2747 of its rules relative to prescriptions for controlled dangerous substances. The 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 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. This Rule is hereby adopted on the day of promulgation.

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.

a. 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.

b. 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.

c. 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 …

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 prescriber, the pharmacist shall dispense a quantity less than the total quantity prescribed. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. No remaining portion of a 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. 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 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;

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), amended LR

M. Joseph Fontenot, Jr.

Executive Director