



Louisiana Board of Pharmacy

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



November 8, 2019

Senator John A. Alario, Jr, President
Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2019-12 ~ Partial Fills of Schedule II Prescriptions

Dear Senator Alario:

The Board has initiated the rulemaking process to amend a portion of its rules for controlled substances to implement the provisions of Act 32 of the 2018 Legislature which permits pharmacies to dispense partial quantities of prescriptions for controlled substances listed in Schedule II. In connection with this regulatory project, the following documents are attached.

• Waiver from Occupational Licensing Review Commission	Page 2
• Notice of Intent	Page 4
• Proposed Rule Changes	Page 5
• Family Impact Statement	Page 6
• Poverty Impact Statement	Page 7
• Provider Impact Statement	Page 8
• Regulatory Flexibility Analysis	Page 9
• Solicitation of Comments	Page 10
• Fiscal & Economic Impact Statement	Page 11
• Act 32 of 2018 Legislature	Page 16

As indicated in the solicitation, we will convene a public hearing on December 27, 2019 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 mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
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 Outreach Services, La. Economic Development
Via Email: Pat.Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

From: [Occupational Licensing Review Commission](#)
To: [Malcolm J. Broussard](#); [Occupational Licensing Review Commission](#)
Cc: [Catherine Brindley](#); [Reg Submission](#)
Subject: RE: Pharmacy Board / [Regulatory Project 2019-12 ~ Partial Fills of Schedule II Prescriptions](#)
Date: Monday, April 22, 2019 10:12:45 AM
Attachments: [image001.png](#)

Malcolm,

The Pharmacy Board may proceed with the normal APA procedures without going through the OLRC for this rule.

Thanks,

Ellen

Ellen Palmintier

Assistant Executive Counsel

Director of Boards & Commissions



225.342.0919

225.208.1531 (fax)

ellen.palmintier@la.gov

gov.louisiana.gov

From: Malcolm J. Broussard [mailto:mbroussard@pharmacy.la.gov]
Sent: Wednesday, April 17, 2019 2:30 PM
To: Occupational Licensing Review Commission
Cc: Catherine Brindley; Reg Submission
Subject: Pharmacy Board / Regulatory Project 2019-12 ~ Partial Fills of Schedule II Prescriptions

The Board of Pharmacy has directed the initiation of the rulemaking process to amend its rules relative to the dispensing of prescriptions for controlled substances listed in Schedule II of the state controlled substance law. In connection with [Regulatory Project 2019-12 ~ Partial Fills of Schedule II Prescriptions](#), you should find the following documents attached to this message:

- Memorandum to Occupational Licensing Review Commission;
- Notice of Intent; and
- Fiscal & Economic Impact Statement.

We look forward to your review of this regulatory project to determine the necessity for its consideration by the Commission. If your determination is that no approval by the Commission is required, we would appreciate your communication to that effect. In the alternative, we thank you for confirming the scheduling of the Commission's consideration.

Please let me know if you have any questions or need additional information.

Thanks,
Malcolm



Malcolm J. Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
Telephone 225.925.6481
mbroussard@pharmacy.la.gov

In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions or board procedures. You may submit such complaints to one or more of the following organizations:

- (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr.; Baton Rouge, LA 70804; 225.925.6496; info@pharmacy.la.gov.
- (2) Committee on House & Governmental Affairs; La. House of Representatives; PO Box 94062; Baton Rouge, LA 70804; 225.342.2403; obriens@legis.la.gov.
- (3) Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183; Baton Rouge, LA 70804; 225.342.9845; s&g@legis.la.gov.

Notice of Intent

Department of Health Board of Pharmacy

Partial Fills of Schedule II Prescriptions (LAC 46:LIII.2747)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend Section 2747 of its rules for controlled substances. Act 32 of the 2018 Legislature amended the controlled substance law to permit the dispensing of partial fills of prescriptions for all medications listed in Schedule II as opposed to only opiate medications listed in Schedule II previously allowed. The proposed rule change will implement the legislation and allow pharmacists to dispense partial fills of prescriptions for all medications listed in Schedule II consistent with federal and state law.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII – Pharmacists

Chapter 27. Controlled Dangerous Substances

§2747. Dispensing Requirements

A. – B.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. ~~If~~ When the pharmacist is unable to supply the full quantity called for in a written (or emergency oral) prescription, ~~and~~ he shall make a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be dispensed within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescriber. No further quantity shall be dispensed beyond 72 hours without a new prescription.

ii. When a partial fill is requested by the patient or the practitioner who wrote the prescription, the pharmacist may 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.

B.5.b. – 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), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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.

I. The effect on the stability of the family.

The proposed rule change will have no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

The proposed rule change will have no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

The proposed rule change will have no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

The proposed rule change will have no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

The proposed rule change will have no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

The proposed rule change 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
FOR ADMINISTRATIVE RULES

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.

I. The effect on household income, assets, and financial security.

The proposed rule change will have no effect on household income, assets, or financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

The proposed rule change will have no effect on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

The proposed rule change will have no effect on employment or workforce development.

IV. The effect on taxes and tax credits.

The proposed rule change will have no effect on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

The proposed rule change will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

PROVIDER IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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:

I. The effect on the staffing level requirements or qualifications required to provide the same level of service.

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

II. The total direct and indirect effect on the cost to the provider to provide the same level of service.

The proposed rule change will have no effect on the cost to the provider to provide the same level of service.

III. The overall effect on the ability of the provider to provide the same level of service.

The proposed rule change will have no effect on the ability of the provider to provide the same level of service.

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

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:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

There are no reporting requirements in the proposed rule change.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule change.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no specific reporting requirements in the proposed rule change.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design or operational standards in the proposed rule change.

V. 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.

SOLICITATION OF COMMENTS

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding the proposed rule amendment. A public hearing to solicit comments and testimony on the proposed rule amendment is scheduled for 9:00 a.m. on Tuesday, November 26, 2019. During the hearing, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day. To request reasonable accommodations for persons with disabilities, please call the Board office at 225.925.6496.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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:

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

The proposed rule change will require the Louisiana Board of Pharmacy to publish the proposed and final rules in the state register, resulting in a one-time cost of \$2,000 for FY 20. There are no other costs or savings for other local or state governmental units. The proposed rule change permits pharmacists to dispense partial fills of prescriptions for all medications listed in Schedule II.

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

The proposed rule change will not affect revenue collections for state or local governmental units.

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

Act 32 of the 2018 Regular Session amended the state controlled substance law to permit pharmacists to dispense partial fills of prescriptions for all medications listed in Schedule II instead of only the opiate medications listed in Schedule II, and to do so in a manner consistent with federal law. The proposed rule change implements the 2018 legislation. When requested by either the prescriber or the patient, the pharmacist may dispense partial fills of such prescriptions, but shall dispense all partial fills no later than 30 days after the date the prescription was issued. The patient may benefit from having less medication on hand to manage. The patient may also benefit from a reduced acquisition cost for a partial fill; however, it is possible the total cost of all partial fills may be higher than the cost of dispensing the entire amount prescribed.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not affect competition or employment.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Malcolm J. Broussard Executive Director	Dept.:	Health
Phone:	(225) 925-6481	Office:	Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title:	Partial Fills of Schedule II Prescriptions
		Effective Date of Rule:	Upon promulgation April 1, 2020 (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)

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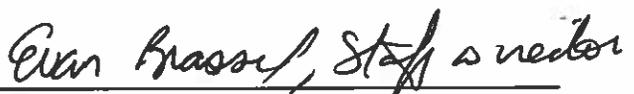
IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not affect competition or employment.


Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

November 7, 2019
Date of Signature


Legislative Fiscal Officer or Designee

11/8/19
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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 change will amend the Board's current rule for the dispensing of prescriptions for controlled substances listed in Schedule II, to allow for the dispensing of partial fills of such prescriptions when requested by the patient or prescriber.

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

Act 32 of the 2018 Legislature amended the state controlled substance law to allow for the dispensing of partial fills for all medications listed in Schedule II, instead of the previous allowance for only opiate medications listed in Schedule II. The proposed rule change will implement the legislation.

- 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.

The Board has allocated \$1,000 each for printing the Notice of Intent and the Final Rule. The Board 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) No. If no, provide justification as to why this rule change should be published at this time.

The Board seeks to update its rules for the dispensing of controlled substances listed in Schedule II, consistent with new state law.

- D. Compliance with Act 820 of the 2008 Regular Session

- (1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", the Board is unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. To the extent any pharmacy licensed by the Board would qualify as a small business, there are 2,003 pharmacies licensed by the Board.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

There are no specific reporting requirements in the proposed rule change. The general recordkeeping requirements for Schedule II prescriptions are consistent with current requirements applicable to all types of pharmacy permits and are federal in origin.

- (3) A statement of the probable effect on impacted small businesses.

The proposed rule change will have no effect on small businesses.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule change.

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?

<u>COSTS</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 2,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 2,000	\$ 0	\$ 0
POSITIONS (#)	0	0	0

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 change will require the Louisiana Board of Pharmacy to publish the proposed and final rules in the state register, resulting in a one-time cost of \$2,000 for FY 20. There are no other costs or savings for other local or state governmental units. The proposed rule change permits pharmacists to dispense partial fills of prescriptions for all medications listed in Schedule II.

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

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 2,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 2,000	\$ 0	\$ 0

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

The Board has sufficient funds available to implement the proposed rule change.

B. COST 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.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

The proposed rule change will have no cost savings for 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?

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
TOTAL	\$ 0	\$ 0	\$ 0

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.

The proposed rule change will not affect revenue collections for state or local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons 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.

Act 32 of the 2018 Regular Session amended the state controlled substance law to permit pharmacists to dispense partial fills of prescriptions for all medications listed in Schedule II instead of only the opiate medications listed in Schedule II, and to do so in a manner consistent with federal law. The proposed rule change implements the 2018 legislation. When requested by either the prescriber or the patient, the pharmacist may dispense partial fills of such prescriptions, but shall dispense all partial fills no later than 30 days after the date the prescription was issued. The patient may benefit from having less medication on hand to manage. The patient may also benefit from a reduced acquisition cost for a partial fill; however, it is possible the total cost of all partial fills may be higher than the cost of dispensing the entire amount prescribed.

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

The proposed rule change will have no effect on receipts or revenue.

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 change will not affect competition or employment.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

November 7, 2019
Date of Signature

SENATE BILL NO. 134

BY SENATOR MILLS

1 AN ACT

2 To amend and reenact R.S. 40:978(A), relative to prescriptions for controlled dangerous
3 substances; to provide for patient options regarding quantity dispensed; to provide
4 technical corrections; and to provide for related matters.

5 Be it enacted by the Legislature of Louisiana:

6 Section 1. R.S. 40:978(A) is hereby amended and reenacted to read as follows:

7 §978. Prescriptions

8 A. Except when dispensed or administered directly by a medical practitioner
9 or administered by a person authorized to administer by such practitioner, other than
10 a pharmacist, to an ultimate user, no controlled dangerous substance included in
11 Schedule II, which is a prescription drug as determined under the Louisiana Revised
12 Statutes of 1950, may be dispensed or administered without either the written
13 prescription of a practitioner, or an electronic prescription order as provided by
14 federal law or regulation, except that in emergency situations, as prescribed by the
15 ~~department~~ **board** by regulation, such drug may be dispensed or administered upon
16 oral prescription reduced promptly to writing and filed by the pharmacist.
17 Prescriptions shall be retained in conformity with the requirements of R.S. 40:976.
18 No prescription for a Schedule II substance may be refilled nor may such
19 prescription be filled more than ninety days after the date of the prescription. **The**
20 **pharmacist filling a prescription for a Schedule II substance may, upon request**

