



Louisiana Board of Pharmacy

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April 8, 2016

Senator John A. Alario, Jr, President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804-9183

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2016-3 ~ Medication Synchronization

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the Board's rules to allow a pharmacist to perform medication synchronization services for his patient, wherein he may adjust the dispensing quantity and refill schedule for multiple medications such that they can all be dispensed on the same day every month, thus reducing the number of trips to the pharmacy for a patient. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent
- Proposed Rule
- Family Impact Statement
- Poverty Impact Statement
- Provider Impact Statement
- Regulatory Flexibility Analysis
- Solicitation of Comments
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing on May 25, 2016 to receive public comments and testimony on this proposed rule change. 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, 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: Req.Submission@la.gov
Reference File

Notice of Intent

**Department of Health and Hospitals
Board of Pharmacy**

Medication Synchronization (LAC 46:LIII.2519)

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 §2519 of its rules. In particular, the board proposes to allow pharmacists to perform medication synchronization services for their patients.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

...

Subchapter B. Prescriptions

...

§2519. Prescription Refills; Medication Synchronization

A. – B.2. ...

C. Medication Synchronization. This term refers 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 refill schedule originally ordered by the prescriber; however, the pharmacist shall not exceed the total quantity prescribed [dispensing quantity multiplied by the total number of fills authorized (original plus refills)], or what is otherwise allowed by law.
2. With respect to prescriptions for controlled substances where refills have been authorized, pharmacists may utilize partial fills, as described in §2747.C.5 of the board's rules, 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, amended LR 33:1133 (June 2007), amended LR

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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.

We anticipate 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.

We anticipate 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.

We anticipate no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

We anticipate no effect on family earnings and the family budget.

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

We anticipate 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.

We anticipate 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.

We anticipate no impact on household income, assets, and financial security.

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

We anticipate no impact on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

We anticipate no impact on employment and workforce development.

IV. The effect on taxes and tax credits.

We anticipate no impact on taxes or tax credits.

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

To the extent a child or other dependent requires multiple prescription medications supplied several times per month at a pharmacy, then medication synchronization services may reduce the number of trips to the pharmacy each month, reducing their transportation costs and possibly improving the benefit received from the medication.

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.

We anticipate no effect on the staffing level requirements or the qualifications for that staff 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.

To the extent that providers incur costs for multiple trips to a pharmacy each month to obtain multiple prescriptions for the same patient, then medication synchronization services may result in a reduction in the number of trips to a pharmacy, thereby reducing their operational costs.

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

We anticipate 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.

The proposed rule does not exempt small businesses from compliance with any of the requirements.

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

There are no reporting deadlines in the proposed rule.

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

There are no reporting requirements in the proposed rule.

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 required in the proposed rule.

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.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Wednesday, May 25, 2016 at 9:00 a.m. in the Board office. At that time, 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.

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 allow pharmacists to perform medication synchronization services for their patients. The proposed rule change will result in a cost of approximately \$2,000 for printing costs. This includes \$1,000 for the proposed rule change in FY 16 and \$1,000 for the final rule in FY 17.

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

There will be no impact on revenue collections of state or local governmental units from the proposed rule change.

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

The persons directly affected by the proposed rule change are those pharmacists who wish to perform medication synchronization services for their patients. The patients who will best benefit from such services are those taking multiple prescription medications from multiple prescribers requiring multiple visits to the pharmacy each month. The pharmacist will be able to adjust the dispensing quantity and refill schedules for the different prescriptions so that all of the prescriptions can be placed on the same schedule, requiring only one visit to the pharmacy each month. There is evidence that patients with simplified schedules are more likely to adhere to such schedules and derive more benefit from their medications. There is no cost to the pharmacist performing such services. Patients may realize some cost savings to the extent this limits their transportation costs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no impact on competition or employment.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: Malcolm J. Broussard Executive Director Dept.: Health and Hospitals
Office: Board of Pharmacy
Phone: (225) 925-6481 Title: Medication Synchronization
Return Address: 3388 Brentwood Drive Effective Date of Rule: July 20, 2016 (est.)
Baton Rouge, LA 70809

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 change will allow pharmacists to perform medication synchronization services for their patients. The proposed rule change will result in a cost of approximately \$2,000 for printing costs. This includes \$1,000 for the proposed rule change in FY 16 and \$1,000 for the final rule in FY 17.

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

There will be no impact on revenue collections of state or local governmental units from the proposed rule change.

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

The persons directly affected by the proposed rule change are those pharmacists who wish to perform medication synchronization services for their patients. The patients who will best benefit from such services are those taking multiple prescription medications from multiple prescribers requiring multiple visits to the pharmacy each month. The pharmacist will be able to adjust the dispensing quantity and refill schedules for the different prescriptions so that all of the prescriptions can be placed on the same schedule, requiring only one visit to the pharmacy each month. There is evidence that patients with simplified schedules are more likely to adhere to such schedules and derive more benefit from their medications. There is no cost to the pharmacist performing such services. Patients may realize some cost savings to the extent this limits their transportation costs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no impact on competition or employment.

Malcolm J. Broussard
Signature of Agency Head or Designee

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

April 8, 2016
Date of Signature

Evan Broussard, Staff Director
Legislative Fiscal Officer or Designee

4/8/17
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 Board proposes to amend §2519 of its rules to allow pharmacists to perform medication synchronization services for their patients, which includes an adjustment of the dispensing quantity and refill schedule for multiple prescription medications so that all of them can be obtained on the same day. Although a pharmacist may currently dispense less than the dispensing quantity ordered, current rules do not permit a pharmacist to dispense more than the dispensing quantity ordered by the prescriber.

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

Recent studies have indicated patients taking multiple prescription medications are more likely to adhere to their medication schedules and have better therapeutic outcomes if those schedules can be simplified. For those patients taking multiple prescriptions issued by multiple prescribers at different times during a month, some patients may require multiple trips to the pharmacy every month. While not problematic for some patients, those with transportation challenges are particularly vulnerable to not getting their prescription refills when needed. In his effort to re-arrange the dispensing schedule for a prescription, the pharmacist may currently dispense less than the dispensing quantity ordered, current rules do not permit a pharmacist to dispense more than that dispensing quantity ordered by the prescriber. The proposed rule change would allow the pharmacist to adjust the dispensing quantity, within certain limits identified in the proposed rule change, and the refill schedule so that multiple prescriptions could be refilled on the same day every month, thus reducing the number of trips per month a patient needs to make to the pharmacy.

- 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 anticipates an expenditure of approximately \$2,000 for the printing of the proposed and final rule – half in FY 16 and half in FY 17. Those funds are budgeted and available from self-generated agency 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) X No. If no, provide justification as to why this rule change should be published at this time.

The Board operates totally on self-generated funds.

- 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”, we are 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 that all of the pharmacies licensed by the Board may meet the statutory definition of a small business, there are 1,981 pharmacies currently 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.

The proposed rule change contains no requirements for reporting or record keeping.

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

The proposed rule change will have no impact 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 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 1,000	\$ 1,000	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 1,000	\$ 1,000	\$ 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 Board has allocated \$1,000 for the printing of the Notice of Intent in FY 16 as well as \$1,000 for the printing of the final rule in FY 17.

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

<u>SOURCE</u>	<u>FY 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 1,000	\$ 1,000	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 1,000	\$ 1,000	\$ 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 budgeted and available to complete the rulemaking project.

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.

There will be no cost savings for local governmental units resulting from the proposed rule change.

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 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</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.

Since the proposed rule change does not impact fees, there will be no impact on revenue collections for state or local governmental units from the proposed rule change.

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.

The persons directly affected by the proposed rule change are those pharmacists who wish to perform medication synchronization services for their patients. The patients who will best benefit from such services are those taking multiple prescription medications from multiple prescribers requiring multiple visits to the pharmacy each month. The pharmacist will be able to adjust the dispensing quantity and refill schedules for the different prescriptions so that all of the prescriptions can be placed on the same schedule, requiring only one visit to the pharmacy each month. There is evidence that patients with simplified schedules are more likely to adhere to such schedules and derive more benefit from their medications. There is no cost to the pharmacist performing such services. To the extent that patients have transportation costs to visit their pharmacy, then patients may realize some cost savings.

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.

There will be no impact on receipts or revenue from the proposed rule change.

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 have no impact on competition or employment.


Signature of Agency Head or Designee

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

April 8, 2016
Date of Signature