



# Louisiana Board of Pharmacy

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August 1, 2016

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

Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2016-3 ~ Medication Synchronization

Dear Senator Alario:

As we indicated in our first report to you on April 8, 2016, the Board is currently amending its 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. Subsequent to our Notice of Intent published in the April 20, 2016 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on May 25, 2016.

We received one written comment prior to the public hearing. It was generally supportive but requested a revision of the original proposal through the insertion of a term synonymous with medication synchronization. i.e., 'refill consolidation'. The Board had no objection to the requested revision. We published the required Potpourri Notice in the June 20, 2016 edition of the Louisiana Register, and then we conducted a second public hearing on July 22, 2016. Just prior to the hearing, we received one written comment from the original commentator, in support of the proposed revision. The Board has determined no further revisions are necessary to the proposed rule, and further, determined it appropriate to move forward with the proposed rule as revised.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the April 2016 Louisiana Register
- Summary of Comments from May 25, 2016 Public Hearing
- Potpourri Notice, as published in the June 2016 Louisiana Register
- Summary of Comments from July 22, 2016 Public Hearing
- Full text of proposed rule as revised

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the revised proposed rule as a Final Rule in the September

20, 2016 edition of the *Louisiana Register*. If you have any questions about the enclosed information or our procedures, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

For the Board:



Malcolm J. Broussard  
Executive Director

cc: Chair, Senate Committee on Health and Welfare – [APA.S-H&W@legis.la.gov](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives – [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Committee on Health and Welfare – [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)  
Editor, *Louisiana Register* – [Reg.Submission@la.gov](mailto:Reg.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 (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 §2519 of its rules. In particular, the board proposes to allow pharmacists to perform medication synchronization services for their patients.

**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, LR 33:1133 (June 2007), LR 42:

**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 are published in the *Louisiana Register* with the proposed agency Rule.

1. The effect on the stability of the family. We anticipate 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. We anticipate no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The effect on the functioning of the family. We anticipate no effect on the functioning of the family.

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

5. The effect on the behavior and personal responsibility of children. We anticipate no effect on the behavior and personal responsibility of children.

6. The ability of the family or a local government to perform the function as contained in the proposed Rule. 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**

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

2. The effect on early childhood development and preschool through postsecondary education development. We anticipate no impact early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. We anticipate no impact on employment and workforce development.

4. The effect on taxes and tax credits. We anticipate no impact on taxes or tax credits.

5. 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.

**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 does not exempt small businesses from compliance with any of the requirements.

2. 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.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements in the proposed Rule.

4. The establishment of performance standards for small businesses to replace design. There are no design or operational standards required in the proposed Rule.

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.

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

3. 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.

#### **Public Comments**

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

#### **Public Hearing**

A public hearing on this proposed Rule is scheduled for Wednesday, May 25, 2016 at 9 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 p.m. that same day.

Malcolm J. Broussard  
Executive Director

### **FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES**

#### **RULE TITLE: Medication Synchronization**

#### **I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT 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 NONGOVERNMENTAL 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  
Executive Director  
1604#058

Evan Brasseaux  
Staff Director  
Legislative Fiscal Office



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Summary of Testimony & Public Comments  
re  
Regulatory Project 2016-3 ~ Medication Synchronization  
at  
May 25, 2016 Public Hearing

1. April 25, 2016 Letter from Mary Staples on behalf of NACDS

Generally supportive, but requests the addition of a synonymous term, 'refill consolidation', along with the term medication synchronization.



April 25, 2016

Malcolm J. Broussard  
Executive Director  
Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700

**Re: Regulatory Project 2016-3 ~ Medication Synchronization**

Dear Mr. Broussard:

On behalf of our members that operate over 718 pharmacies in the state of Louisiana, the National Association of Chain Drug Stores (NACDS) is writing in support of Regulatory Project 2016-3 ~ Medication Synchronization. Regulatory Project 2016-3 would amend Section 2519 of Title 46 of the Louisiana Administrative Code, which would allow pharmacists to perform medication synchronization services.

We believe that allowing pharmacies to perform medication synchronization services not only reduces medication waste, but also reduces the incidence of poor healthcare outcomes that result from decreased medication adherence. Poor medication adherence costs the U.S. healthcare system \$290 billion annually – 13% of total healthcare expenditures– and results in avoidable and costly health complications, worsening of disease progression, increased emergency room visits, and hospital stays. This inadequate medication adherence rate is associated with about \$47 billion annually for drug-related hospitalizations, and an estimated 40% of nursing home admissions.

Medication synchronization can help to improve medication adherence. A recent study by Virginia Commonwealth University found that, in comparison to control subjects, patients in the medication synchronization program experienced stronger communication with the complete health care team, had 2.8 more refills/year resulting in 84 more days of medication and had 3.4 to 6.1 times greater odds of adherence. Those not enrolled in the medication synchronization program had a 52% to 73% greater likelihood of discontinuing their medication therapy. In another study, researchers at Harvard Medical School found that when medications were not synchronized, patients had adherence rates that were 8.4% lower than patients for which medications were synchronized. Similarly, in a study at George Washington University, medical researchers identified medication synchronization as an important component of improving adherence, noting: “[t]he Medicaid population would benefit from a policy that allowed for flexibility in medication supplies to improve refill consolidation [synchronization]. This would allow a physician or pharmacist to consider appropriate adjustments and improve adherence in this population.”

**Suggested Language Changes**

As we reviewed the proposed rule, we also identified that the described process whereby a pharmacist may proactively adjust the medication dispensing quantity of a patient’s prescription could be applicable outside of the act of synchronizing multiple medications on a patient’s profile. Under the term

“Medication Refill Consolidation,” a pharmacist would be able to help improve medication adherence for a given patient, even if the patient is taking just one medication. Therefore, we are suggesting the following edits so that patients in both categories could benefit:

§2519. Prescription Refills; Medication Synchronization *and Refill Consolidation*

A. – B.2. ...

C. Medication Synchronization *and Refill Consolidation*. ~~This term refers~~ These terms refer to a service which a pharmacist may perform for his patient, at the request of the patient, wherein he may proactively adjust the medication dispensing quantity and/or the refill schedule of a prescription in order to manage the patient’s medication therapy, with the goal of improved medication adherence by the patient

NACDS appreciates the opportunity to provide the perspective of our membership on this issue. For all of the reasons explained above, chain pharmacy supports Regulatory Project 2016-3 and the proposed changes to allow for medication synchronization.

Sincerely,

A handwritten signature in black ink that reads "Mary Staples". The signature is written in a cursive, flowing style.

Mary Staples  
Director, State Government Affairs

# Potpourri

## POTPOURRI

### Department of Health Board of Pharmacy

#### Public Hearing—Substantive Changes to a Proposed Rule Medication Synchronization (LAC 46:LIII.2519)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy published its Notice of Intent in the April 2016 edition of the *Louisiana Register*, specifying its proposal to amend §2519 of its rules to authorize pharmacists to perform a service known as medication synchronization with regard to the dispensing of refills. As indicated in the notice, the board conducted a public hearing on May 25, 2016 to receive comments and testimony on the proposal.

The board received one request, to add a synonym of medication synchronization, refill consolidation, to the title and body of the referenced Section. The board has no objection to the request and now seeks to revise the original proposal.

The Legislative Fiscal Office has opined the proposed revision requires no modification of the original Fiscal and Economic Impact Statement which they approved.

#### Title 46

### PROFESSIONAL AND OCCUPATIONAL STANDARDS

#### Part LIII. Pharmacists

#### Chapter 25. Prescriptions, Drugs, and Devices

#### Subchapter B. Prescriptions

#### §2519. Prescription Refills; Medication Synchronization and Refill Consolidation

A. - B.2. ...

C. Medication Synchronization and Refill Consolidation.

These terms 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, LR 33:1133 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 42:

#### Public Comments

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule as well as these proposed revisions to the original proposal.

#### Public Hearing

A public hearing on this proposed revision to the original proposal is scheduled for Friday, July 22, 2016 at 9 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 p.m. that same day.

Malcolm J. Broussard  
Executive Director

1606#054



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Summary of Testimony & Public Comments  
re  
Regulatory Project 2016-3 ~ Medication Synchronization  
at  
July 22, 2016 Public Hearing

1. July 19, 2016 Letter from Mary Staples on behalf of NACDS  
Supportive of revised proposal.

July 19, 2016

Malcolm J. Broussard  
Executive Director  
Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700

**Re: 46 LAC LIII.2519 ~ Medication Synchronization**

Dear Mr. Broussard:

On behalf of our members that operate pharmacies throughout the state of Louisiana, the National Association of Chain Drug Stores (NACDS) is writing in support of the proposed rule that would amend Section 2519 of Title 46 of the Louisiana Administrative Code, allowing pharmacists to perform medication synchronization services.

We believe that allowing pharmacies to perform medication synchronization services not only reduces medication waste, but also reduces the incidence of poor healthcare outcomes that result from decreased medication adherence. Poor medication adherence costs the U.S. healthcare system \$290 billion annually – 13% of total healthcare expenditures– and results in avoidable and costly health complications, worsening of disease progression, increased emergency room visits, and hospital stays. This inadequate medication adherence rate is associated with about \$47 billion annually for drug-related hospitalizations, and an estimated 40% of nursing home admissions.

NACDS applauds the Board for updating the rules to allow for medication synchronization.

Sincerely,



Mary Staples  
Director, State Government Affairs

# 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 and Refill Consolidation

A. – B.2. ...

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  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.

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