



Louisiana Board of Pharmacy

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



July 7, 2022

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2022-10 ~ Compounding

Dear Senator Cortez:

The Louisiana Board of Pharmacy seeks to amend its rule relative to standards for pharmacy compounding. The proposed rule change removes the reference to a specific edition of the United States Pharmacopeia-National Formulary thereby making the current edition applicable for pharmacy compounding.

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

- Notice of Intent Page 2
- Fiscal & Economic Impact Statement Page 5

As indicated in the solicitation, we will convene a public hearing on August 26, 2022 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr.
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Director, Community Competitiveness & Small Business Services, La. Economic Development
Via Email: Witty@la.gov
Editor, *Louisiana Register*
Via Email: Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health Board of Pharmacy

Compounding (LAC 46:LIII.2535)

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 §2535 of its rules relative to standards for pharmacy compounding. The proposed rule changes in §2535 removes the reference to a specific edition of the United States Pharmacopeia-National Formulary thereby making the current edition applicable for pharmacy compounding.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. A pharmacy shall have written procedures as necessary for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality, and purity they are represented to possess.
2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 (FDCA) as subsequently amended, the current edition of Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the ~~2014 edition of the~~ United States Pharmacopeia-National Formulary (~~USP 37—NF 32~~).

A.2.a – G.2.i. ...

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 23:1316 (October 1997), LR 29:2105 (October 2003), effective January 1, 2004, LR 41:97 (January 2015), amended by the Department of Health, Board of Pharmacy, LR 42:891 (June 2016), LR 46:577 (April 2020), amended LR

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The Effect on the Stability of the Family. The proposed rule changes will have no effect on the stability of the family.
2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule changes will have no effect on the authority and rights of parents regarding the education or supervision of their children.
3. The Effect on the Functioning of the Family. The proposed rule changes will have no effect on the functioning of the family.
4. The Effect on Family Earnings and Family Budget. The proposed rule changes will have no effect on family earnings or family budget.
5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule changes will have no effect on the behavior or personal responsibility of children.
6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed rule changes will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rules.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule changes will have no effect on household income, assets, or financial security.
2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule changes will have no effect on early childhood development or preschool through postsecondary education development.
3. The Effect on Employment and Workforce Development. The proposed rule changes will have no effect on employment or workforce development.
4. The Effect on Taxes and Tax Credits. The proposed rule changes will have no effect on taxes or tax credits.
5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule changes will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

Small Business Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule changes do not establish less stringent compliance requirements for small business.
2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule changes do not establish less stringent 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 offer no 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: Compounding

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

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$500 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 of state or local governmental units.

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

The proposed rule changes remove the references to a specific edition of the United States Pharmacopeia-National Formulary (USP-NF). Since the current compounding standards are contained in the 2014 edition of the USP-NF, removing the reference to the 2014 edition in rule has no current impact on directly affected persons, small businesses, or non-governmental groups.

However, USP efforts to update the relevant chapters for compounding have been underway since 2019. USP does not have an anticipated date for publication of the proposed revision but will provide advance notice of at least six months prior to the anticipated effective date of the proposed revision. The cost for a pharmacy to comply with any revised standards will vary by pharmacy and are indeterminable until finalized USP-NF standards are released.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

Given the universal nature of the requirement, the proposed rule changes will have no effect on competition or employment.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

Person Preparing Statement:	M. Joseph Fontenot, Jr. Executive Director	Dept.: Dept. of Health
Telephone:	225.925.6481	Office: Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title: Compounding
		Effective Date of Rule: Upon promulgation Dec. 20, 2022 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

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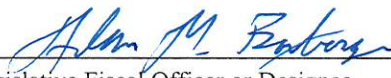
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Joe Fontenot
Digitally signed by Joe Fontenot
DN: cn=Joe Fontenot, o=Louisiana Board of Pharmacy,
ou=Executive Director, email=jfontenot@pharmacy.la.gov, c=US
Date: 2022.07.01 12:06:05 -05'00'
Signature of Agency Head or Designee

M. Joseph Fontenot, Jr. Executive Director
Typed Name and Title of Agency Head

July 01, 2022
Date of Signature


Legislative Fiscal Officer or Designee

7/1/22
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule changes in §2535 removes reference to a specific edition of the United States Pharmacopeia-National Formulary thereby making the current edition applicable for pharmacy compounding. A copy of the notice of intent is appended.

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

When the rule was promulgated referencing a specific edition, the Board of Pharmacy was under the impression a specific edition was required. Being made aware that is not the case, the Board determined it was in the public's best interest to remove a specific edition to this federally enforceable standard thereby making the current edition applicable.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated \$500 for printing the Notice of Intent and the Rule. LBP 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 NO. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule changes are in the public's best interest.

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 23	FY 24	FY 25
Personal Services	\$500		
Operating Expenses			
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$500		None
POSITIONS (#)	None	None	None

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed rule changes will require LBP to print the Notice of Intent and Rule in the state register at a cost of \$500 in FY 2023.

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

SOURCE	FY 23	FY 24	FY 25
State General Fund			
Agency Self-Generated	\$500		
Dedicated			
Federal Funds			
Other (Specify)			

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

TOTAL	\$500	None
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4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule changes.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.
2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

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

The proposed rule changes do not impact local governmental units.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

- A. What increase (decrease) in revenues can be anticipated from the proposed action?

The proposed rule changes will not affect revenue collections of state or local governmental units.

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

*Specify the particular fund being impacted.

- B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

- A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule changes in §2535 remove the reference to a specific edition of the United States Pharmacopeia-National Formulary (USP-NF). Since the current official versions of USP-NF for compounding (sterile and non-sterile) are contained in the 2014 edition, removing the reference to the 2014 edition in rule has no current impact on directly affected persons, small businesses, or non-governmental groups. However, USP efforts to update the relevant chapters for compounding has been underway with proposals since 2019, but USP does not have an anticipated date for a final publication as indicated in a May 14, 2022 notification. When a date for final publication becomes official, those pharmacies not in compliance with the updated standard would be expected to become compliant in a timeline provided by the Board. The costs to pharmacies at a future time is indeterminable since there is no final publication available, only a proposal.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income

**FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET**

resulting from this rule or rule change to these groups.

The proposed rule changes should have no impact on receipts and/or income to these groups.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule changes should have no impact on competition or employment in the public and private sectors.