



# Louisiana Board of Pharmacy

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December 6, 2022

Senator P. Page Cortez  
President, Louisiana Senate  
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 2022-10 (Summary Report) ~ Compounding

Dear Senator Cortez:

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

Subsequent to the publication of our Notice of Intent in the July 2022 edition of the *Louisiana Register*, we conducted a public hearing on August 26 to receive comments and testimony on the proposed rule. We received no comments or testimony. The Board subsequently determined no revisions were warranted. On November 3<sup>rd</sup> the Department of Justice's Occupational Licensing Review Program approved the proposed amendment to the regulation for adoption. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the July 2022 *Louisiana Register* – Page 2
- Record from the August 26, 2022 Public Hearing – Page 5
- Full text of proposed rule, as intended for publication in the *Louisiana Register* – Page 6

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rules without amendment as a Rule in the January 20, 2023 edition of the *Louisiana Register* with an immediate effective date. If you have any questions about the enclosed information or our procedures, please contact me directly at [jfontenot@pharmacy.la.gov](mailto: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](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives - Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee - Via Email: [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)  
Editor, *Louisiana Register* - Via Email: [Reg.Submission@la.gov](mailto: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 United States Pharmacopeia-National Formulary.

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 GOVERNMENT UNITS (Summary)**

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

M. Joseph Fontenot Jr.  
Executive Director  
2207#059

Alan M. Boxberger  
Interim Legislative Fiscal Officer  
Legislative Fiscal Office



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Summary of Testimony & Public Comments

Regulatory Project 2022-10 ~ Compounding  
at  
August 26, 2022 Public Hearing

*No comments or testimony received.*

## **Rule**

### **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 amended §2535 of its rules relative to standards for pharmacy compounding. The amendment removes the reference to a specific edition of the United States Pharmacopeia-National Formulary thereby making the current edition applicable for pharmacy compounding. This Rule is hereby adopted on the day of promulgation.

## **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 United States Pharmacopeia-National Formulary.

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M. Joseph Fontenot, Jr.

Executive Director